AcademyHealth

February 9, 2015

The Honorable Fred Upton
Chairman, Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20510

The Honorable Diana DeGette
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20510

Re: Response to 21st Century Cures Initiative Discussion Draft

AcademyHealth welcomes the opportunity to provide input to the Committee on Energy & Commerce on its 21st Century Cures Initiative Discussion Document. We are the professional home of more than 5,000 health services researchers, policy analysts, and practitioners, whose work helps us understand and improve our complex health system, and thus enable better health outcomes for more people at greater value.

The 21st Century Cures Initiative is in and of itself a positive indicator that Congress is making a true effort to build science and evidence and drive innovative ideas that will benefit patients and society at large. AcademyHealth strongly believes in the bill's foundational mission "to accelerate the discovery, development, and delivery of 21st century cures," but would encourage lawmakers to place equal emphasis on each phase—discovery, development, *and* delivery. It isn't enough to develop cures; for patients to actually benefit from these cures, we must also understand how to most effectively and efficiently deliver them to patients, which has implications for health care quality, costs, access, and ultimately patient outcomes.

As the Committee continues to revise its 21st Century Cures Initiative, we urge members to ensure the legislation is reflective of the whole research continuum, considering the role of health services research in addition to basic and clinical research. While medical research discovers cures for diseases, health services research discovers innovative cures for the health system. Health services research diagnoses problems in health care and public health delivery and identifies solutions. Innovations from this field of research can be used right now by patients, health care providers, public health professionals, hospitals, employers, and public and private payers to improve care today.

AcademyHealth was encouraged by several provisions in this discussion document, and among those, would place emphasis on the following areas:

- **Patients should be at the center of care, with their perspectives incorporated from the outset.**

  AcademyHealth greatly appreciated the Committee's inclusion of incorporating patient perspectives into the regulatory process. We feel strongly that patients should be empowered to make informed choices about what treatments work best for them, and a core component of this is dependent upon the evaluation and proper communication of interventions and their relative safety, effectiveness, and cost.

- **Responsible communication of scientific developments is critical for the advancement of research.**

  AcademyHealth supports the flow of information for research and the infrastructure and environment needed for its dissemination. To that end, we encourage Congress to consider policies that enhance—and do not unnecessarily restrict—the production of research and policies that enhance the quality, availability, timeliness, and affordability of data and tools used to produce research.

- **Lawmakers should make their best effort to reduce administrative burdens that unnecessarily hinder scientific innovation and progress.**

  Streamlining the Institutional Review Board (IRB) process will help ensure that individuals who participate in research are protected and that the data with which we work are collected, used, and stored ethically and appropriately. The reform of this policy will relieve administrative burden while assuring the rigorous and potentially enhanced protection of human subjects.

- **AcademyHealth supports enhancing the evidence base, and moving knowledge into action.**

  We value the Committee's inclusion of provisions that provide for the use of evidence within policymaking and practice, recognizing the importance of research to improve health care and care delivery.

In sum, even with more, better, and faster drug discoveries, innovations will fall short of their potential if we don't determine how best to deploy them to physicians and patients and determine what works, for whom, under what circumstances, and at what cost. Health services research helps maximize the return on investment in basic and clinical research, ensuring that patients have access to and truly benefit from drug discoveries and medical advances.

We look forward to working with the Committee to determine how to best integrate health services research into the 21st Century Cures Initiative, and how we can ensure these discoveries reach their full potential.

If you have any questions about these comments, please contact me directly at 202.292.6747 or lisa.simpson@academyhealth.org.

Sincerely,

Lisa Simpson, M.B., B.Ch., M.P.H., F.A.A.P.

President and CEO
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February 20, 2015

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton,

On behalf of the medical imaging research community, the Academy of Radiology Research thanks you for your leadership to improve the discovery, development and delivery of new treatments and diagnostics for Americans.

We greatly appreciate the opportunity to review the discussion draft of the 21st Century Cures legislation, and thank the Committee for the inclusion of a number of topics already suggested by the imaging science community last year. The draft bill is a wonderfully comprehensive effort that rightly addresses many obstacles in the discovery pipeline. In this regard, we would appreciate the opportunity to offer a few additional thoughts for your consideration as the legislation nears completion.

Section 1001 – Patient Experience Data; Lead: Chairman Emeritus Joe Pitts (R-PA) and Rep. Cathy McMorris Rodgers (R-WA)

Action: page 12 under (i) Methodological considerations for the collection of patient experience data…." add fifth criteria (red):

"(V) the impact of diagnostic uncertainty"

Rationale: This section is excellent and the imaging community is thankful for the Committee's work to include valuable patient input data into the FDA's risk-benefit algorithms. However, the patient and provider value of an early and accurate diagnosis is not reflected in the current legislative language. Including the proposed criteria above will help ensure that diagnostics' sponsors have approved methodologies for acquiring and submitting patient experience data on this critical juncture in the care plan.

Section 1021; Evidentiary Standards for the Review of Requests for the Qualification of Surrogate Endpoints; Lead: Rep. Cathy McMorris Rodgers (R-WA)

[redacted]

Comment: As a leader in biomarker ex[redacted]ration, the imaging research community greatly appreciates the Committee's recognition of the need for clear guidelines for biomarker qualification using surrogate endpoints. Imaging is providing an earlier and more personalized diagnosis, tailored treatment staging, and real-time monitoring of treatment efficacy – all of which can depend on surrogate endpoints to confirm effectiveness. Having clear and efficient guidelines on the qualification of surrogate endpoints will accelerate all

phases of the care plan, from diagnosis through treatment and recovery. We thank the Committee for its thoughtful consideration of this potentially transformative topic.

Section 1081; Breakthrough Devices; Lead: Chairman Emeritus Joe Pitts (R-PA)

Action: add in the following language (red):
"(A) has the potential to, compared to existing approved alternatives, reduce or eliminate the need for hospitalization, reduce diagnostic uncertainty, improve treatment monitoring, decrease risk to the patient, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long term clinical efficiencies;"

Rationale: We are greatly appreciative of the Committee's work to expedite the regulatory process for breakthrough medical devices, including advanced and personalized medical imaging diagnostics. Given the importance of this section, and as with Section 1001, we would recommend language that ensures the section is implemented by the Secretary with the inclusion of breakthrough diagnostics.

Section 1082 – CMS Coverage of Breakthrough Devices (to be supplied)

Comment: We thank the Committee for recognizing all of the obstacles for clinical adoption of breakthrough devices, and would appreciate the opportunity to comment on this section when available.

Section 1123 – Expanded Access; Lead: Reps. Michael McCaul (R-TX) and Michael C. Burgess, M.D. (R-TX):

Comment: Like investigational drugs, patient access barriers to unapproved and/or investigational device and diagnostics can also exist. We recommend adding the words "and devices" after each instance of the work "drugs" in Sections 1121-1125 to ensure that the Secretary addresses the barriers to individual patient access for unapproved diagnostics and devices in addition to investigational drug products. Additionally, we recommend identifying membership requirements from the device and/or diagnostics community in the Task Force section (1124) – one member from a company with more than 250 employees and one member from a company with less than 250 employees – in order to adequately address the barriers towards expanded patient access to unapproved but potentially life-saving investigational devices and diagnostics.

Section 2001 – 21st Century Cures Consortium; lead: Rep. Cathy McMorris Rodgers (R-WA)

Action: add subsection below (red):
"(4) establish a strategic agenda for accelerating the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients;

(A) this agenda shall adopt a metrics-driven approach to reduce overall burden of disease and increase economic impact when possible. Metrics that help guide the agenda shall include--

a. Overall cost of disease to the healthcare system and the percent of the Consortium's resources spent in specific areas,
b. Individual and family costs of specific diseases,
c. Quality-adjusted life years gained due to expected advances,
d. Innovation output metrics from areas of science, including established patent and licensing output measures, from programmatic areas,

e. New products, start up companies, and jobs expected from programmatic areas.

(B) The Consortium can work with other federal entities with similar aims, such as the National Science and Technology Council under the Office of Science and Technology Policy, to incorporate consensus recommendations in the area of science and innovation policy.

Rationale: Federal research and development agencies have taken steps in the last few years to increase their data collection capabilities in order to improve the evidence base for how we prioritize resources across areas of science (particularly the OSTP Science of Science Policy interagency working group). The Cures Consortium's goals may be enhanced by the integration of a metrics-driven approach that seeks the dual aim of improving human health and maximizing the economic returns from publicly funded research.

Sec 2021 - Medical Product Innovation Advisory Commission; Lead: Rep. Cathy McMorris Rodgers (R-WA)

Action: add subsection below (red):
"(C) THE CYCLE OF DISCOVERY, DEVELOPMENT, AND DELIVERY OF MEDICAL PRODUCTS AND INNOVATION.—Specifically, the Commission shall assess—
"(i) the cycle of discovery, development, and delivery of new medical products in the United States, and the policies affecting such cycle; ~~and~~
"(ii) what steps may be taken to accelerate the cycle and facilitate the transition between the phases of the cycle; and
"(III) what metrics, in terms of public health and economic impact, will be employed to measure success. Potential metrics shall include:

(C) Anticipated reductions to the overall cost of disease to the healthcare system;
(D) Anticipated reductions to individual and family costs of disease;
(E) Anticipated quality-adjusted life years gained;
(F) Patent and licensing rates from areas of science, agencies or NIH Institutes; and
(G) New product, start up companies, jobs, and exports expected from various areas of science, agencies or NIH Institutes

Rationale: This section would take important qualitative and quantitative steps to accelerate the discovery and delivery of innovative new medical products. Consistent with our recommendation in the previous section (2001), this section may also want to stipulate that the Commission ensures an evidence-based, metrics-driven approach to their reports and recommendations. By adding the proposed language above, the Secretary's goals would reflect the language later in the section that provides instructions for collecting and utilizing data.

SEC. 2121. Authority for Coverage with Evidence Development for Medical Devices Under the Medicare Program

Action:
S[redacted]R COVERAGE WITH EVIDENCE DEVELOPMENT FOR MEDICAL DEVICES UNDER THE MEDICARE PROGRAM

(a) EXCEPTION TO REASONABLE AND NECESSARY REQUIREMENT.—Section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. 1395y(a)(1)(A)) is amended by inserting "or a CED item or service (as described in section1861(iii))" after "(as described in section 1861(ddd)(1))".

(b) DEFINITION OF CED ITEM OR SERVICE.—Section 1861 of the Social Security Act (42 U.S.C.

1395x) is amended by adding at the end the following new subsection:
'(iii) CED ITEM OR SERVICE.—
''(1) IN GENERAL.—The term 'CED item or service' means an item or service that is for coverage with evidence development (as described in paragraph (2)).
'(2) COVERAGE WITH EVIDENCE DEVELOPMENT.—For purposes of paragraph (1), an item or service is for coverage with evidence development if—
''(A) the item or service is furnished to individuals as part of a clinical study performed to determine whether the furnishing of such item or service improves the health outcomes of such individuals, as determined under paragraph (3); and
''(B) the furnishing of the item or service to the individual is determined by the Secretary to be reasonable and necessary to the carrying out of such clinical study.
'(3) DETERMINATION OF IMPROVED HEALTH OUTCOMES.—For purposes of paragraph (2)(A), a determination of whether the furnishing to individuals of items or services improves the health outcomes of such individuals shall be determined by assessing whether the furnishing of such items or services improves the—
'(A) diagnosis or treatment of illnesses or injuries of such individuals (as compared to the diagnosis or treatment of illnesses or injuries of comparable individuals who are not so furnished such items or services); ~~or~~
''(B) functioning of malformed body members of such individuals (as compared to the functioning of malformed body members of comparable individuals who are not so furnished such items or services), or
(C) ability of patients, caregivers, or treating physicians to develop more appropriate care plans, as determined by approved patient experience data.
(4) DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE THE CED DETERMINATION FRAMEWORK.—
'(A) IN GENERAL.—Not later than two years after the date of the enactment of this subsection, the Secretary shall establish and implement processes under which—
''(a) an entity seeking to develop patient experience data may submit to the Secretary—
''(i) initial research concepts for feedback from the Secretary; and
''(ii) with respect to patient experience data collected by the entity, draft guidance documents, completed data, and summaries and analyses of such data;
''(B) the Secretary may request such an entity to submit such documents and summaries; and
''(C) patient experience data may be developed and used to enhance the improved outcomes determination framework under subsection (3).
''(5) PATIENT EXPERIENCE DATA.—In this subsection, the term 'patient experience data' means data collected by patients, parents, caregivers, patient advocacy organizations, disease research foundations, or medical researchers that is intended to provide information about the experience of patients with a disease, or the impact a disease and management of the disease has on the lives of patients or their caregivers.''
(6) COVERAGE – services and items provided under the CED framework shall be covered in a manner consistent with the indications for use in the proposed coverage policy."

Rationale: We appreciate the Committee's work to better define CMS's authority in regard to coverage with evidence development (CED). The CED framework presented has the potential to

provide an expedited and scientific approach to the approval of emerging technologies. In the experience of the imaging science community, this framework could also take a patient-centered approach to the determination of "improved health outcomes" by including the same type of patient experience data that is proposed in Section 1001. The addition of (C), and its accompanying Section (4), would recognize the value of items or services that improve the ability to patients, families and providers to establish the best care plan – as informed by the collection and evaluation of real-world patient experience data. Section (6) would also ensure that during this evaluative period, patients participating in a trial have full coverage and access to the items and services being studied by providing coverage in the same manner that it would be if the item or service were approved.

Section 2281 – High Risk, High Reward Research; Lead: Andy Harris (R-MD)

Action: add subsection (red):
"The director of each national research institute, in collaboration with other scientists, shall—
(1) establish programs to conduct or support research projects that pursue innovative approaches to major contemporary challenges in biomedical research that involve inherent high risk, but have the potential to lead to breakthroughs; ~~and~~
(2) set aside a specific percentage of funding, to be determined by the Director of NIH for each national research institute, for such projects; and
(3) in developing these programs, consult with the Director of the National Institute for Biomedical Imaging and Bioengineering in regard to the Quantum Grant program, which has successfully implemented this approach to innovative breakthroughs."

Rationale: The goal of the Quantum Grant program from the National Institute for Biomedical Imaging and Bioengineering (NIBIB) is "to achieve a profound (quantum) advance over present-day approaches to the prevention, detection, diagnosis, and/or treatment of a major disease or national public health problem. Major biomedical technologies, emerging from the interface of the engineering, physical, and life sciences such as MRI imaging, endoscopic devices for minimally invasive surgery, the cochlear implant, and the pacemaker have had a profound impact on human health and quality of life. In many cases, realization of a quantum impact from a new biomedical technology can only be achieved if the needed intellectual and financial resources are focused on a specific targeted project in a concerted fashion. The NIBIB Quantum Program is intended to support development of biomedical technologies that will result in a profound paradigm shift in prevention, detection, diagnosis, and/ or treatment of a major disease or national public health problem."

Considering the synergy between the goals of Section 2281 and the NIBIB Quantum Grant program, NIBIB might be an ideal candidate to provide guidance to other Institutes on successfully implementing such a program.

Section 4001 – NIH Research Strategic Investment Plan; Lead: Andy Harris (R-MD)

Action (page 241): add language and subsection (red):
"[redacted]e efficient and effective focus of biomedical research in a manner that leverages the best scientific and technological opportunities through a deliberative planning process;
"(B) identifies areas, to be known as strategic focus areas, in which the resources of the National Institutes of Health can best contribute to the goal of expanding knowledge on human health, or have a demonstrable economic impact, in the United States through biomedical research;
"(C) includes measurable objectives for each such strategic focus area, such as:

(i) Anticipated reductions to the overall burden of disease within the healthcare system,
(ii) Anticipated reductions to individual and family costs of disease,
(iii) Quality-adjusted life years gained,
(iv) Patent and licensing output rates from programmatic areas or NIH Institutes,
(v) New products, start up companies, and jobs expected from programmatic areas or NIH Institutes,

(D) and works with other federal entities with similar aims, such as the National Science and Technology Council under the Office of Science and Technology Policy, to incorporate consensus recommendations in the area of science and innovation policy.

Rationale: Given the efforts of both public and private sector researchers to better measure the health and economic impact of publicly funded research (including the work of the OSTP Science of Science Policy interagency working group), NIH should begin to incorporate these empirical results into the strategic planning process. Doing so would result in a national research agenda that is optimized to both improve human health while stimulating the nation's innovation economy in the biotechnology sector. These additions would complement the dual-aim language (economic and health) later in the section (bottom of page 242) and ensure the adoption of such an approach from NIH in the planning process.

Section 4005 – GAO Report On Common Fund; Lead: Chairman Emeritus Joe Barton (R-TX)

Action: add language below (red):
(a) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the Common Fund established under section 402A(c) of the Public Health Service Act (42 U.S.C. 282a(c)).
(b) CONTENTS.—The report under subsection (a) shall include an analysis of how amounts reserved under such section have been used, ~~and~~ the impact of that funding on the each of the areas that received funding, the growth of the program compared to other national research institutes and centers, and the programmatic impact on support for investigator initiated awards at non-Common Fund programs.

Rationale: Although the Common Fund has supported some wonderful examples of Big Science initiatives, its growth over the past decade has stood out compared to the rest of NIH. Since 2004, the Office of the Director (OD) has grown 343%, while the average for all other NIH Institutes and Centers has been just 5.7% – resulting in a decade-long annual growth rate of 14.1% for the OD versus 0.33% for the remaining Institutes and Centers. Due to this allocation shift to the OD, nine core NIH grant-making Institutes, including NCI, NHLBI, NIDCR, NIDDK, NEI, and NIAMS never actually achieved the "doubling" of their budgets from 1999-2003, and with the continued emphasis on the OD, still have not doubled from their baseline 1998 appropriation even today. Today, if the Office of the Director were considered an Institute, it would now be the 7th largest according to the proposed FY2016 President's Budget.

This focus on Big Science over the past decade has left investigator-initiated projects severely l[redacted]As such, Institutes and Centers are struggling to maintain their p[redacted]R01 pool of funding – w[redacted]ely regarded as the lifeblood of American academic science and the mechanism that has spurred the most Nobel Prizes among NIH investigators. Therefore, the Committee's request for a GAO report on the Common Fund should ensure that the program's goals and activities are reviewed within the context of these allocation shifts and opportunity costs to other core NIH Institutes and Centers.

Section 4007 – Additional Funding for the NIH Common Fund

Action: strike section

Rationale: Due to the concerns above, it may be prudent to hold off on additional increases to the NIH Common Fund until the GAO report has been issued.

Section 4010 – Medical Imaging Research Initiative (newly proposed section)

Action: add new Section:
"Section 4010 – Medical Imaging Research Initiative
"Not later than 12 months after the date of enactment of this Act, and annually thereafter, the Office of Science and Technology Policy shall submit to Congress a report on the the Medical Imaging Research Initiative. Such report shall include information on —

(1) Multiagency efforts to accelerate highly innovative and multidisciplinary programs that develop powerful new imaging technologies for more tailored clinical solutions;
(2) Greater standardization across all imaging research systems and platforms to promote reproducibility, reduce duplication, and ensure the highest quality clinical research data;
(3) The development of a cadre of federal imaging scientists that can advise on key issues of national priority and address issues pertaining to federal imaging R&D;
(4) The cultivation of a diverse STEM and clinical imaging R&D workforce;
(5) Programs and policies to cement U.S. competitiveness in this high-skilled, export-driven sector."

Rationale: The report for the Fiscal Year 2015 Omnibus Appropriations bill included instructions for the implementation of a Medical Imaging Research Initiative (MIRI) within the Office of Science and Technology Policy. The goals for the MIRI are to accelerate this highly innovative and multidisciplinary area of science, while cementing the U.S.'s manufacturing and export leadership of these powerful technologies. Given the high number of federal research agencies involved in the research, development, translation, regulation, and clinical implementation – as well as recent econometric research that showed this area of research was one of the federal government's most productive in terms of innovation metrics – an effort to coordinate these programs was recognized. While the OSTP and NIH have signaled that they will be implementing the MIRI in 2015, the public health and domestic economic significance warrants a regular report to Congress on these important programmatic efforts.

Once again, thank you to the Committee members for undertaking such an important, comprehensive and transparent effort. We hope these additions capture the interest and obstacles for the advanced imaging research and development arena, and hope they can be included in the final iteration of the bill.

Sincerely,

[redacted]

Jonathan S. Lewin, MD
President
Academy of Radiology Research

[redacted]

Executive Director
Academy of Radiology Research

February 11, 2015

The Honorable Fred Upton
Chairman, House Energy and Commerce
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

RE: APRN Groups Express Support and Recommendations for the "21st Century Cures Act" Discussion Document

Dear Chairman Upton:

On behalf of the member organizations of the Advanced Practice Registered Nurse (APRN) Workgroup, we commend your publication of the "21st Century Cures Act" discussion document. We appreciate your request for public comment and are pleased to offer our recommendations in support of provider-neutral language throughout the proposal as well as in the telemedicine provision, and our support for the young scientists (Sec. 2261) and local and national coverage decision reform (Sec. 4161) proposals.

The APRN Workgroup is comprised of organizations representing Nurse Practitioners delivering primary, specialized and community healthcare; Certified Registered Nurse Anesthetists who provide the full range of anesthesia services as well as chronic pain management; Certified Nurse-Midwives expert in primary care, maternal and women's health; and Clinical Nurse Specialists offering acute, chronic, specialty and community healthcare services. Totaling more than 340,000 healthcare professionals, including two of the ten largest categories of Medicare Part B provider specialties according to Medicare claims data, our primary interests are patient wellness and improving patient access to safe and cost-effective healthcare services. In every setting and region, for every population particularly among the rural and medically underserved, America's growing numbers of highly educated APRNs expand healthcare access and quality improvement in the United States and promote cost-effective healthcare delivery.

Consistent Use of Provider-Neutral Language

Our first recommendation is that the "21st Century Cures Act" should include provider-neutral language throughout. Where it makes assignments or ascribes benefits to physicians, it should also include APRNs and other providers. Healthcare leadership, care delivery, research and innovation are provided in the 21st Century healthcare system by a full range of healthcare professionals, therefore, legislation intended to advance innovations within the healthcare system should not deter the contributions of all qualified healthcare professionals. We request that the following instances of "physician" in the discussion document dated January 26, 2015, be corrected to "physician or other healthcare providers," including but not limited to: page 22 line 1; page 84 line 6; page 85 line 11; page 145 lines 12, 13 and 15; page 164 line 2; page 189 line 11; page 315 line 4; page 321 lines 10 and 16; and page 371 line 7. Further, the following

references to "medicine" should be replaced with neutral language encompassing all qualified professionals. Examples of such language include: "healthcare" or "medicine and healthcare" and should be inserted in the following instances: page 3 the title of Title II, and the title of Subtitle C and Sec. 2041; page 5 the title of Subtitle Q; page 6 the title of Subtitle I; page 7 the title of Subtitle O; and the same titles and subtitles where they occur in the discussion document.

Title II Subtitle O "Helping Young Emerging Scientists"

We commend the inclusion of investments in young emerging scientists. According to the American Association of Colleges of Nursing, in the last academic year, there were 5,145 nursing students in research focused doctoral programs. These terminal degree programs prepare nursing students to pursue intellectual inquiry and conduct independent research for the purpose of extending knowledge. During their programs, they are prepared to drive change and innovation that will improve health outcomes nationally and globally. Like other scientists, competition is intense after these nurse researchers graduate and pursue programs of research as principle investigators. It is important that emerging scientists with strong research questions have opportunities to build a long career as investigators. Section 2261, clearly denotes that these funds would be available to all institutes and centers, which includes the National Institute of Nursing Research (NINR). Research funded at NINR helps to integrate biology and behavior as well as design new technology and tools. NINR's research fosters advances in nursing practice, improves patient care, works to eliminate health disparities, and attracts new students to the profession. Support for emerging scientists is an investment in the scientific endeavors that will generate new knowledge for better health.

Title IV Subsection H "Local and National Coverage Decision Reforms"

The APRN workgroup supports the updates and requirements for public comment for Medicare Administrative Contractors' (MAC) local coverage determinations (LCDs) identified in Sec. 4161. Establishing a more timely and transparent process provides healthcare professionals the opportunity to share how the proposal would have a positive or negative impact and receive advanced notice of potential changes to their practice. Currently under Medicare policy, a Carrier Advisory Committee (CAC) consists only of physicians.[1] We would recommend updating this outdated statutory condition to include APRNs so that a variety of perspectives from qualified healthcare professionals could be heard. This revised process also allows MACs to modernize as practice styles change and new evidence-based research and practice techniques are established. A more inclusive LCD process assures patients and providers' voices are heard and the highest quality of care is provided.

Title IV Subtitle I "Telemedicine"

Telehealth services are increasingly provided by healthcare professionals who are not physicians, including APRNs. And so first, the provision should be titled "telehealth" or a similar term, to reflect current common usage, and to remove any mistaken impression that the provision pertains solely to physicians. Second, provisions relating to medical board compacts should apply similarly to nursing board compacts (page 299 line 1 et seq). Third, the list of covered telehealth services selected by the Secretary (page 293 line 14 et seq) must expressly exclude services that

do not provide patients with greater quality or access, such as remote "tele-supervision" or "tele-collaboration" that physicians may seek to charge unnecessary oversight of APRNs. There is no clinical or economic value for such "tele-supervision" or "tele-collaboration" services to patients or the public and Medicare should not pay for them.

We applaud the efforts of the House Energy and Commerce Committee for their work on the 21st Century Cures initiative and for addressing necessary improvements to accelerate the delivery and discovery of quality treatments and cures for patients through Secs. 2261 and 4161. We also praise the Committee's dedication to improving patient access to healthcare services through telemedicine, yet caution the potential for unnecessary tele-supervision of APRNs services. We appreciate your consideration of our views on these topics and thank you. If you have any questions, please contact Frank Purcell at 202-484-8400 or via email at fpurcell@aanadc.com.

Sincerely,

American Association of Colleges of Nursing (AACN)

American Association of Nurse Anesthetists (AANA)

American Association of Nurse Practitioners (AANP)

American Colleges of Nurse Midwives (ACNM)

American Nurses Association (ANA)

Gerontological Advance Practice Nurses Association (GAPNA)

National Association of Clinical Nurse Specialists (NACNS)

National Association of Pediatric Nurse Practitioners (NAPNAP)

cc: Ranking Member Frank Pallone, House Energy and Commerce Committee
Chairman Joe Pitts, House Energy and Commerce Subcommittee on Health
Vice Chair Brett Guthrie, House Energy and Commerce Subcommittee on Health
Congresswoman Diana DeGette, House Energy and Commerce Committee
Congressman Andy Harris, House Appropriations Committee

[1] Medicare Program Integrity Manual Ch. 13, Sec. 13.8.1.2 and Exhibit 3.1. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf, and http://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/downloads/pim83exhibits.pdf.

AKROS

AKROS PHARMA INC.

February 11, 2015

By E-Mail

The Honorable Fred Upton
Chairman
Energy & Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Diane DeGette
Energy & Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Re: 21st Century Cures Initiative: Comments in Response to Request for Feedback on a Modernized Framework for Innovative Diagnostic Tests

Dear Chairman Upton and Ranking Member DeGette:

Akros Pharma Inc. (Akros) applauds the United States House of Representatives Committee on Energy and Commerce for launching the 21st Century Cures Initiative, and submits the following comments on Question 11 in the Committee's December 9, 2014 Request for Feedback. Akros is a small, dynamic company based in Princeton, NJ, with a commitment to developing new pharmaceutical products for the US and global market. In conjunction with our parent company and its partners, we have developed novel active ingredients that are found in FDA-approved products for the treatment of HIV-1 and metastatic melanoma. We currently have active development programs in diabetes, autoimmune disease, and anemia.

The Committee's July 23, 2014, roundtable on personalized medicine underscored the need for incentives to encourage the development of new, more accurate and more efficient diagnostic tests. The potential for medicines targeted to specific patients, based on information obtained through a companion diagnostic, is enormous and the impact on public health would be revolutionary. Developing these tests, however, is difficult and costly. Companion diagnostics are also subject to a complex regulatory process, requiring coordination of both drug and medical device regulation. To encourage companies to invest in a lengthy development and regulatory review process, new incentives are needed.

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For that reason, we urge the Committee to include effective incentives for companies to develop companion diagnostics for targeted medicines within the 21st Century Cures Act. Based on the discussion draft that the Committee released on January 27, 2015, it appears that those incentives could be placed in Title II, Subtitle J: Modernizing Regulation of Diagnostics.

We recommend that the Committee adopt the approach proposed in the MODDERN Cures Act, H.R. 3116, as introduced in the previous Congress. The proposed approach is modeled after the Best Pharmaceuticals for Children Act (the BPCA), which grants a six-month extension of any existing marketing exclusivity to sponsors that perform pediatric studies that FDA requests. Six months of additional marketing exclusivity, in that context, proved to provide a substantial benefit to pharmaceutical sponsors and the number of pediatric studies performed has significantly increased since the BPCA was enacted.

Further evidence that marketing exclusivity can serve as a powerful incentive are the Hatch-Waxman Act, the Orphan Drug Act, and the Generating Antibiotics Incentives Now Act (the GAIN Act). We need incentives with the same type of power to bring about the change that medicines coupled with companion diagnostics promise. In addition to saving lives, coupling medicines with companion diagnostics will also save substantial costs to the healthcare system by reducing the amount of money spent on off-target drugs and biologics that are less effective or ineffective. Furthermore, the use of off-target drugs and biologics increases financial burdens on the healthcare system due to the costs associated with adverse events without significantly improving patient outcomes.

The MODDERN Cures Act would provide an exclusivity extension – much like the BPCA and the GAIN Act – to any exclusivity period that exists for a drug or biological product coupled with a companion diagnostic. A twelve month period would be awarded for companies that develop a companion diagnostic contemporaneously with a new drug or biologic, and a six month extension would be awarded for a diagnostic developed separately from the original approval of the product. The longer period for a dual development program is warranted, given the added regulatory and scientific risk of managing the investigation of two distinctly regulated medical products at the same time. There is also a significant benefit to patients in having a companion diagnostic available at the time a drug or biological product is first approved.

To ensure that the full benefit of the incentive is realized, however, the provisions of the MODDERN Cures Act involving innovative diagnostics should be refined, as follows:

- Addition of definitions of key terms, such as "diagnostic test," that will ensure that only actual and appropriate companion diagnostics receive the incentive;

- Clarification of the meaning of the phrase "developed by, or with the participation of the manufacturer or sponsor" to make clear the exact level of sponsor or manufacturer involvement necessary to qualify the targeted medicine for exclusivity;

- Clarification of the phrase "provides for or improves" identification of the patient population or of the most appropriate treatment option for a patient population;

- Revision to the definition of "medicines" to make clear that combination products, as well as drug-drug combinations and biologic-biologic combinations can qualify for the incentive;

- Clarification of the limits of the Secretary's discretion to determine that an extension is not warranted.

Akros looks forward to working with the Committee to provide specific recommendations on language that would improve the scope and implementation of the exclusivity incentive. We would also appreciate the opportunity to discuss these matters with the Committee as it prepares a discussion draft of Subtitle J of Title II.

We sincerely appreciate the opportunity to comment on the 21st Century Cures initiative, as well as the collaborative approach that the Committee is taking to formulate this important legislation.

Sincerely,

[redacted]

Timothy Babcock, J.D.
Vice President, Intellectual Property
Akros Pharma, Inc.

ALLIANCE FOR
HCPCS II CODING REFORM
creating a transparent, fair and predictable system

February 13, 2015

VIA ELECTRONIC MAIL

Chairman Fred Upton
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

RE: Comments to 21st Century Cures Act: Suggested HCPCS Coding Process Reforms

Dear Chairman Upton and Ranking Member Pallone,

The current Healthcare Common Procedure Coding System (HCPCS) coding process for Level II alpha-numeric codes used by Medicare, Medicaid, and private health plans (particularly for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS)) is not transparent, understandable or predictable. Over many years, this has created strong barriers to appropriate coverage and reimbursement for new technologies and products. The current process has a chilling effect on innovation that drives researchers and R&D investments away from DMEPOS, ultimately compromising access to quality care for millions of Medicare beneficiaries and other individuals. Although this process is administered by the Centers for Medicare and Medicaid Services, this badly flawed process impacts Medicare and all payers using the uniform code set. Reform is needed to ensure the goals of a meaningful code set are met, namely, uniformity in billing, appropriate coverage and reimbursement policies, and patient access to quality care.

Included below are recommendations for your consideration to be included in the 21st Century Cures Act when it is introduced in final form. Given the overall purpose of that proposed legislation, these recommendations for HCPCS Level II coding reform fit well within the confines of that proposed legislation. The members of the Alliance would be pleased to speak with you at your convenience about our concerns regarding the HCPCS coding process as well as about our recommendations.

The Alliance for HCPCS II Coding Reform ("Alliance") was formed in May 2008 to seek improvements to the HCPCS coding process so that it is fair, transparent, predictable, accurate, understandable, timely, accountable, efficient and independent of any individual payer's coverage and payment considerations. An improved HCPCS Level II coding process would allow meaningful consumer access to technology, regardless of payer. The Alliance is comprised of key law firms, lobbying firms, associations, coalitions, medical device companies and

reimbursement consulting companies with expertise in HCPCS coding who recognize the need to take action to reform the HCPCS coding system.

We have met over the years with the Centers for Medicare and Medicaid Services (CMS) senior staff; unfortunately, they have been reluctant to make the significant changes that would be meaningful to the process. This is why we believe that it is imperative to have legislative action on this important issue.

The fundamental problems we have identified with the current HCPCS decision process are as follows:

1. The current HCPCS Level II code set includes broadly defined codes that are ambiguous and imprecise, resulting in dissimilar technologies being lumped into the same code. This challenges coverage policy development and creates barriers to comparative effectiveness research that could provide evidence to inform improvements to coverage and policy decisions. In addition, it leads to improper payment determinations that oftentimes create barriers to access of medically necessary devices and technologies.

2. The coding process is not transparent, predictable, or timely. The criteria used to justify issuing or modifying codes are often undefined, have never been subject to public notice and comment, and seem to be applied inconsistently from year to year. In addition, there is no assurance that coding decisions give appropriate weight to scientific and clinical trial evidence that may distinguish an item or service from existing items or services with HCPCS codes. The composition of the HCPCS Workgroup at CMS has never been disclosed publicly, and the Workgroup has never included stakeholders in the decision-making process. CMS also does not allow for advance notice and stakeholder feedback when it decides unilaterally to delete or modify certain existing HCPCS codes outside the external application process. Finally, there is no reconsideration/appeal process other than resubmission of the application in the next annual coding cycle; this insulates the process from any form of accountability and causes delays of at least one year in patient access to these products.

3. The coding process improperly commingles Medicare coverage decisions with coding decisions. The factors involved in justifying creation of a new billing code are separate and distinct from the factors involved in justifying coverage of a particular device or technology to meet the needs of a specific payer's enrollees. In fact, this distinction is well-recognized in the laws and precedents that apply to the Medicare program. Nevertheless, the current process results in CMS making coverage decisions for all payers and often overlooks non-government-supported health plans that have coverage and payment policies that may be different from Medicare and serve different patient populations.

4. Outside of the HCPCS Coding process (where existing codes are modified and new codes are created) the coding verification process administered by the Pricing, Data Analysis, and Coding (PDAC) contractor is also in need of reform in order for manufacturers, suppliers, and providers to obtain clear guidance on accurate coding. This process also needs to separate coverage from coding criteria in establishing coding verification.

To address these significant problems with the HCPCS Level II coding process, we offer the following recommendations:

1. Recommendation: Increase Transparency of Coding Decisions.

i. HCPCS Workgroup Responsibilities: There should be a mechanism in place for each representative on the HCPCS Workgroup to obtain comments regarding HCPCS coding needs and information on the submitted applications so as to represent their constituency. Representatives should have the explicit responsibility to listen to stakeholder groups and individuals who wish to inform them of facts and circumstances involving coding decisions.

ii. Public Accountability: CMS should publish the names, affiliations, and titles of the CMS HCPCS Workgroup members. The identities of the Workgroup members should be a matter of public record and CMS should explicitly permit direct contact between coding applicants and Workgroup members throughout the year.

iii. Robust Representation on the HCPCS Workgroup: A more robust representation of Medicaid, Veterans Health Administration (VA), and commercial payers should be involved in the coding process to meet the needs of diverse populations. CMS should meaningfully engage, *throughout the entire coding process*, Medicaid, VA, and commercial payers to a greater extent to obtain their opinions on current HCPCS code applications and determine their HCPCS coding needs. CMS should clarify and formalize the process for Medicaid and commercial payers to ensure that their coding needs or program operating needs are identified and given adequate consideration by the HCPCS Working Group.

iv. Detail Reasons for Denial: Reasons for denial currently used by CMS in this process should be explained with greater specificity. To be fair, CMS has made improvements in this area over the past several years. The reasons for denial form the basis for the changes to the applicant's revised coding application for the following cycle and as a result these reasons therefore need to be sufficiently detailed to provide clarity and avoid unnecessary waste of time and resources. If CMS denies an application for a new HCPCS code, the letter should specify both the rationale for the decision not to issue a new code and explain what information the applicant needs to provide in future applications to achieve a favorable code result.

v. One-on-One Consultation: CMS should provide applicants with an opportunity to meet in person with CMS Workgroup staff before a preliminary decision is made to ensure that the HCPCS Coding Workgroup fully understands the devices and technologies being considered, and so that applicants may advance their rationale for a new code or codes.

Mechanism for Applicant to Withdraw HCPCS Code Application. CMS should work with stakeholders to develop a timeline, process and circumstances under which an applicant may withdraw an application for the current HCPCS coding year.

2. Recommendation: Clearly Separate the Criteria Used to Establish a New HCPCS Code from Criteria Used to Establish Coverage Policy.

i. Purge Coverage Criteria from Coding Decisions: Revise CMS's current *coding* "Decision Tree" to reflect that coding decisions are based on criteria that are separate and distinct from the criteria used to make *coverage* decisions for the same device or product. We recommend the following criteria to establish a new code. The device or product:

1. Performs a different function (does something clinically different for the patient) than a previously coded product; OR

2. Operates differently; OR

3. Is a distinct technology (e.g., components, materials of construction, structural features, size, mechanism of action are distinctly different from existing technology); OR

4. Meets a distinct patient or clinical need (e.g., there is a distinct patient population that benefits from the use of this device, or there are significant clinical indications or uses that are distinct from existing codes.)

ii. Conformity with New Coding Criteria: CMS should be required to revise its HCPCS Coding "Decision Tree" to conform with the criteria listed immediately above and the additional suggestions below:

1. Provide a clearer definition of what constitutes a "national program operating need" (in order to establish a new billing code) by commercial payers, Medicaid programs, as well as other payers and stakeholders by developing specific criteria to be met. We recommend revising the definition of the term "national program operating need" so that if one sector (defined as a payer, i.e., one Medicaid program, one commercial plan) supports the issuance of a new code, a national program operating need shall be recognized. To validate this request, the applicant would submit one letter from the one payer to CMS as part of the HCPCS application. In addition, the current requirement that an applicant demonstrate significant therapeutic distinction should be removed because it often comingles coverage with coding considerations; instead, the new decision tree criteria described above should be substituted.
2. Add additional objective data to support the sales volume criteria that would demonstrate significant product demand in the marketplace such as sales trend reports and product feasibility studies. (*See* new definition for sales volume criteria.).
3. Restrict the current practice of revising code descriptors to expand the scope of an existing code; this practice makes the coding system inaccurate and/or imprecise, leading to opportunities for abuse.

3. Recommendation: Establish an Appeals Process to Provide Independent Review/Reconsideration of Coding Decisions.

i. Establish the Right to Appeal Coding Decisions: HCPCS coding applicants who receive adverse coding decisions should have a right to appeal the decision to a HCPCS Coding Appeals Board. The applicant should be granted an informal, in-person hearing with the appeals board within the 90-day period and prior to a final decision being made, providing the applicant with an opportunity to discuss the application, answer any questions, and address CMS' previous decision rationale. The appeals board should be comprised of a representative sample of individuals who serve on the HCPCS Workgroup, including Medicaid, VA, and private insurance representation as well as either the Director or Deputy Director of the CMS Chronic Care Policy Group to provide historical context and expertise to the coding decision. The board should be required to solicit external physicians and other health care professionals and suppliers with expertise in the specific subject of the coding application at issue to assist the appeals board in rendering a final coding decision. If the coding decision is changed as a result of the appeal, the new or revised code and fee schedule would be implemented in the next HCPCS quarterly update.

4. Recommendation: PDAC Coding Verification Process Must be Improved

i. Proper Notice and Comment of All Coding Changes: All revisions, deletions, consolidations and changes to code criteria of HCPCS codes announced by the PDAC must first be published on the DME MAC websites and supplier publications in draft form with reasonable time for public comment before any HCPCS coding change becomes final and effective. This would not rise to the level of public notice and comment procedures under the Administrative Procedures Act.

ii. Greater Access to the PDAC: PDAC officials should meet with coding verification applicants to discuss the product(s) at issue. In addition, key PDAC decision makers should be required to keep periodic office hours at CMS central in Baltimore, Maryland in order to permit small businesses and manufacturers to more easily engage the PDAC in coding verification discussions.

iii. Pediatric Coding: CMS should develop a mechanism for coding verifications for pediatric products or otherwise work with Medicaid programs to eliminate the requirements for obtaining PDAC code verification. (For example, the PDAC currently declines to conduct coding verification for pediatric products.)

iv. Coverage Information Separate from Coding: Consistent with our recommended standard for separate consideration of coverage and coding for new and revised codes, the PDAC should never use coverage information in the code verification process.

The Alliance for HCPCS II Coding Reform appreciates the opportunity to submit these comments to you for consideration of inclusion in the 21st Century Cures Act. We stand ready to meet with you to discuss these issue in more depth at your convenience. Thank you.

Sincerely,

Marcia Nusgart R.Ph.
Alliance for HCPCS Coding Reform Participants who include but are not limited to:*

Grant Bagley; ADVI (formerly HillCo Health)
Jennifer Hutter; J.D. Hutter and Associates LLC
Stuart S. Kurlander; Latham & Watkins LLP
Marcia Nusgart; Coalition of Wound Care Manufacturers
Lynn Shapiro Snyder, Robert Wanerman; Epstein Becker and Green
Peter Thomas; Powers, Pyles, Sutter and Verville PC
Debra Wells; Wells Health Group

CC: Representative G.K. Butterfield
Representative Diane DeGette
Representative Renee Ellmers
Representative Gene Green
Representative Joseph Pitts

Alliance of Specialty Medicine

Sound Policy. Quality Care.

February 20, 2015

The Honorable Fred Upton
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
United States House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515

RE: 21st Century Cures Comments on January 26, 2015 Discussion Draft

Dear Chairman Upton and Representative DeGette:

The Alliance of Specialty Medicine appreciates the opportunity to provide comments in response to the 21st Century Cures January 26th discussion draft (F:\WPB\CO14R\CURES\CONSOLIDATED). The Alliance is a coalition of national medical societies representing specialty physicians in the U.S. and is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. We greatly appreciate your leadership to improve the discovery, development and delivery that support continued innovation in our health care system.

The Alliance offers specific comments on the following provisions included in the discussion draft.

TITLE I—PUTTING PATIENTS FIRST BY INCORPORATING THEIR PERSPECTIVES INTO THE REGULATORY PROCESS AND ADDRESSING UNMET NEEDS

SUBTITLE B—SURROGATE ENDPOINT QUALIFICATION AND UTILIZATION (SECTIONS 1021-1024)
The Alliance supports establishing a transparent process at FDA with specified timeframes for the development of evidentiary standards and the review and qualification of surrogate endpoints for broader utilization in regulatory decision-making. It is critical to support innovation in the drugs, biologicals and devices that diagnose, treat and monitor our patients. We support efforts to help expedite the development and approval of safe and effective drugs for unmet needs. **We would encourage inclusion of these provisions in the final legislative language if clarification is made regarding data ownership.**

The Alliance supports the focus on public-private-partnerships, but has concerns about the possible implications regarding ownership of the data collected through these private-public partnerships. We believe that patient data collected through privately-administered registries should be the sole property of the private entity administering the registry, and **we believe that public agency access to those data should be at the discretion of their private entity owner. We respectfully request clarification on**

ownership of data and stand ready to work with the committee based on the collective experience our member organizations have in establishing and running registries.

SUBTITLE H—FACILITATING RESPONSIBLE COMMUNICATION OF SCIENTIFIC AND MEDICAL DEVELOPMENTS

The FDA does not allow pharmaceutical, biological and medical device companies to actively distribute key clinical information, even if it is related to the on-label indication, unless it is explicitly referenced in the package insert. By limiting the sharing of information, physicians are hampered in their ability to gain all of the firm scientific rationale and sound medical evidence needed to treat patients. The Alliance is **pleased to see that the committee included a placeholder** to address this issue and stands ready to work with you to clarify and rationalize these rules so that scientific and medical developments on pharmaceuticals, biologicals and medical devices can be shared with physicians, with appropriate safeguards, in order to optimize patient care. We recommend that the committee develop standards for qualifying real world data, through a public process; expand the current process of review of materials beyond what is included in the package insert to also cover other key data, such as subpopulation, pharmacoeconomic or comparative cost data; and ensure a timely review process for such information.

TITLE II—BUILDING THE FOUNDATION FOR 21ST CENTURY MEDICINE, INCLUDING HELPING YOUNG SCIENTISTS

SUBTITLE B—MEDICAL PRODUCT INNOVATION ADVISORY COMMISSION
SEC. 2021. MEDICAL PRODUCT INNOVATION ADVISORY COMMISSION.

The Alliance urges you to slightly modify this provision which would create the Medical Product Innovation Advisory Commission. Similar to the Medicare Payment Advisory Commission (MedPAC), this Commission will advise Congress, analyze medical product innovation in the United States and recommend policies to accelerate the discovery, development, and delivery of new medical products. We appreciate that the membership of the Commission requires the participation of physicians to ensure the first-hand input of those on the front lines of patient care. However, we believe that this provision should also apply to products with indications that expand or change, and not merely apply to new products coming to market. Because it is important to continue to support innovation, the Alliance **supports maintaining this provision with the suggested modification to strike "new" in the section**.

SUBTITLE F—BUILDING A 21ST CENTURY DATA SHARING FRAMEWORK
PART 1—IMPROVING CLINICAL TRIAL DATA OPPORTUNITIES FOR PATIENTS
SEC. 2081. STANDARDIZATION OF DATA IN CLINICAL TRIAL REGISTRY DATA BANK ON ELIGIBILITY FOR CLINICAL TRIALS.

This section would establish a data sharing framework to enable patients and physicians to better identify ongoing clinical trials. The Alliance agrees that the clinical trials registry should be easy for physicians and patients to access and that entries and results data should be easily compared in a standardized format employing comprehensive health care terminology that includes clinical trial inclusion and exclusion criteria. We appreciate that the HHS Secretary is required to convene a meeting of stakeholders (including physicians) to provide advice on enhancements to the clinical trial registry data bank. **The Alliance encourages you to retain this provision.**

PART 3—BUILDING A 21ST CENTURY CLINICAL DATA SHARING SYSTEM
SEC. 2085(b). ACCESS TO MEDICARE DATA BY QCDRs.
The Alliance supports the requirement that HHS make Medicare, Medicaid, and CHIP claims data available to Qualified Clinical Data Registries (QCDRs), but we request that the committee broaden this provision so that it ensures access to such data for all clinical data registries (i.e., not just QCDRs). Furthermore, we are concerned that the discussion document requires the Secretary to charge a fee to cover the cost of such data. Running a registry already requires a significant investment of resources, a challenge that is heightened by the fact that many registries are run by non-profit entities. Registries should have unfettered access to federal claims data, which, when combined with more robust clinical data, can result in more accurate evaluations of quality and value performance.

SEC. 2087. HIPAA COMMON RULE EXCEPTION.
The Alliance appreciates the inclusion of language requiring an exception to the Common Rule for registries and other entities that collect identifiable data, but have no direct interaction with patients and comply with all applicable HIPAA regulations. Current regulations for informed consent are outdated and create unnecessary regulatory barriers that limit the ability of registries to engage in prospective, systematic tracking of practice patterns and patient outcomes that lead to better care.

SEC. 2091. COMMISSION ON DATA SHARING FOR RESEARCH AND DEVELOPMENT.
This provision would establish a Commission on Data Sharing for Research and Development. While the Alliance supports efforts to ensure the integrity of clinical registry data and the need for guidelines related to the use of registries, we are concerned that overly prescriptive standards may result in a one-size-fits-all approach to registries and ignore the fluid and diverse nature of registries and the unique needs of different specialties and different patient populations. Government involvement in this issue should be restricted to setting standards that ensure an adequate infrastructure for the collection of registry data, such as ensuring that EHR vendors are interoperable with registries, protecting data privacy and security, and providing funding to promote innovative registry practices. The registry community, which is already well coalesced, should remain responsible for reaching consensus on other standards related to how registries work.

If a Commission is established for this purpose, we urge the Committee to revise the language in this section to specify that the Commission is advisory only; representative of relevant stakeholders, including physicians and others directly involved in registry design and implementation; and that appointments must be non-partisan and non-political (i.e., the Speaker of the House should not make these appointments; instead we recommend that the U.S. Government Accountability Office take on this task, similar to MedPAC appointments). The role of the advisory board should be to highlight best practices and potentially inform the Secretary's recommendations in Sec. 2092

SEC. 2092. RECOMMENDATIONS FOR DEVELOPMENT AND USE OF CLINICAL REGISTRIES
The Alliance appreciates many of the recommendations proposed under this section, including the promotion of bidirectional, interoperable exchange of information between EHRs and registries. As mentioned earlier, it is critical that the Secretary adopt and better enforce interoperability standards to ensure the seamless exchange of information between certified EHRs and qualified clinical data registries. The current language seems to put the onus on registries, while the most significant current barrier to integration of EHR data in registries is EHR vendor refusal to share data with registries or charging excessive fees for such access. We urge Congress to mandate that EHR vendors adopt interoperability standards as a condition of receiving federal certification.

TITLE III—MODERNIZING CLINICAL TRIALS

SUBTITLE A—CLINICAL RESEARCH MODERNIZATION

SEC. 3001. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

The Alliance applauds efforts to streamline the institutional review board (IRB) process, particularly for clinical trials conducted at multiple sites. This provision is consistent with the recently released draft NIH policy on the use of a single IRB for multi-site research and **we urge the committee to maintain this provision.**

SEC. 3002. USE OF INSTITUTIONAL REVIEW BOARDS FOR REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS.

The Alliance also **supports this provision** as it allows review by a centralized IRB.

TITLE IV—ACCELERATING THE DISCOVERY, DEVELOPMENT, AND DELIVERY CYCLE AND CONTINUING 21ST CENTURY INNOVATION AT NIH, FDA, CDC, AND CMS

SUBTITLE I—TELEMEDICINE

SEC. 4181. ADVANCING TELEHEALTH OPPORTUNITIES IN MEDICARE.

The Alliance appreciates the inclusion of this provision to advance opportunities for telemedicine and new technologies to improve the delivery of quality health care services and improve Medicare beneficiaries' access to specialty physicians. The Alliance agrees with the sense of the Congress encouraging States to collaborate, through the use of State medical board compacts, to create common licensure requirements for providing telehealth services. This is necessary to facilitate multistate practices and allow for specialty physicians to provide services across State lines.

SUBTITLE O—ACCELERATING INNOVATION IN MEDICINE

SEC. 4301. ESTABLISHMENT OF MANUFACTURER OPT-OUT PROGRAM FOR MEDICAL DEVICES.

Under the current structure for making coverage decisions, CMS evaluates newly FDA-approved products based on clinical evidence and comparative effectiveness to other already CMS-covered products. Because it can be difficult to compile adequate clinical evidence at the time that a product is initially approved or cleared by the FDA, cutting edge medical technologies are often subject to limited coverage or inadequate reimbursement under Medicare, especially when these products and procedures warrant greater reimbursement than Medicare will offer without supporting data. As a result, manufacturers sometimes choose not to make these products or procedures available in the United States, or when they do, beneficiaries interested in self-paying face discouraging bureaucracy, time delays, and uncertainty.

This provision seeks to address this problem by providing an option for medical device manufacturers to "opt-out" of the Medicare coverage determination process for at least three years to allow time to obtain the necessary clinical evidence in support of a stronger case for a future Medicare coverage decision. This change would reduce the obstacles Medicare beneficiaries face in trying to access these new technologies, ensure they are informed of the costs, and allow them to self-pay before Medicare coverage is sought by the manufacturer. By allowing beneficiaries to have this option, clinical studies and data collection can take place and these innovative technologies will help patients in the United States, instead of solely in foreign countries. **The Alliance encourages the committee to maintain this option for Medicare beneficiaries in the final bill.**

SUBTITLE Q—ENSURING LOCAL MEDICARE ADMINISTRATIVE CONTRACTORS EVALUATE DATA RELATED TO CATEGORY III CODES

SEC. 4341. ENSURING LOCAL MEDICARE ADMINISTRATIVE CONTRACTORS EVALUATE DATA RELATED TO CATEGORY III CODES.

The Alliance would like to work with the Committee on this provision as you refine the discussion draft. We are concerned that the Medicare Administrative Contractors (MACs) automatically put Category III codes on their non-covered lists because they are categorized as "new technology" and resulting non-coverage adversely impacts patient access to potentially life-saving treatments and technologies. The Alliance would like to better understand this provision; specifically what is meant by "all data" and whether this would include data from observational research registries, peer-reviewed journals, abstracts, presentations at conferences, etc. We are concerned that the language may be too broad and would suggest that the MACs review all reference studies and literature considered by the AMA CPT Editorial Panel when the Category III code was approved in addition to any peer-reviewed, published data and data from observational research registries to date.

SUBTITLE S—CONTINUING MEDICAL EDUCATION SUNSHINE EXEMPTION*

SEC. 4381. EXEMPTING FROM MANUFACTURER TRANSPARENCY REPORTING CERTAIN TRANSFERS USED FOR EDUCATIONAL PURPOSES.

The Alliance **strongly supports the inclusion of this provision** which clarifies that peer-reviewed journals, journal reprints, journal supplements, and medical textbooks are excluded from the reporting requirement under the Sunshine Act. Physicians must have access to the most up-to-date independent medical knowledge to support their delivery of high quality patient care.

The Alliance appreciates this ongoing process toward the introduction of bipartisan legislation and looks forward to continuing to work with you on this initiative. Please let us know if our expertise may be of assistance, especially as you seek additional feedback or would like assistance in developing content for the placeholders.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists
Society for Cardiovascular Angiography and Interventions
Society for Excellence in Eyecare

CC: Members of the House Energy and Commerce Committee

**NASS has not yet taken a formal position on Sec. 4381 and remains neutral on the provision.*

ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

February 5, 2015

Chairman Fred Upton
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am writing today in support of the Ellmers-Butterfield provision in the 21st Century Cures Discussion Draft bill, "Subtitle G—Disposable Medical Technologies." As wound care health providers, we understand the importance of allowing providers and patients to access the most appropriate technologies. Current Medicare law is outdated and shortsighted by not covering certain disposable technologies in the home care setting that may be more cost-effective and promote greater patient compliance.

The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our clinical specialty societies and organizations not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

Medical technology has advanced and, not surprisingly, clinical practice and standards of care have evolved along with these advancements. As these changes occur, Medicare payment policy also must evolve to support home-based, patient-friendly technologies. Excluding disposable medical technology from Medicare coverage ignores the evolution of medical care, restricts provider choice, and places undue burdens on Medicare beneficiaries. Providers and patients simply have no choice but to use more expensive, bulky traditional durable medical equipment (DME) or seek care in more expensive institutional settings. This raises Medicare costs and stifles innovation. By providing coverage for disposable medical technology in the home, Medicare would help ensure continuity of care between care settings, facilitate better outcomes, and reduce costs.

With the health care delivery system becoming more integrated, it is imperative that providers are able to prescribe and use the most appropriate technologies in the least expensive setting specific to a patient's particular condition and health status, particularly if they are easier to use and as effective. Current Medicare

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DME payment policy could cause beneficiaries to face a gap in care as they transition from the hospital to the home because a product they receive in the hospital may not be covered once they return home.

One example of such technology is disposable negative pressure wound therapy (NPWT). This technology delivers all the proven benefits of NPWT, but in a vastly more portable and patient-friendly manner. Disposable NPWT typically works without a bulky canister to collect exudate from wounds and is an ideal therapy to help patients transition to home- or community-based care. The extreme portability, discreetness, and comfort of a disposable product are the main advantages over traditional NPWT. It helps clinicians to treat wounds, reduce complications, and cut costs while at the same time allowing patients to experience their daily activities with less pain.

We urge the Energy & Commerce Committee to maintain this important provision in the 21st Century Cures bill as the Committee continues to refine the legislation.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

CC: Representative G.K. Butterfield
Representative Diane DeGette
Representative Renee Ellmers
Representative Gene Green
Representative Joseph Pitts

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February 13, 2015

The Honorable Fred Upton
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Re: 21st Century Cures Initiative discussion document

Dear Chairman Upton and Representative DeGette:

The Alzheimer's Association appreciates the opportunity to comment on the discussion document and applauds you both for your visionary leadership in developing the 21st Century Cures Initiative. The Association also recognizes the many Representatives who have contributed to this overarching discussion document and are grateful for the opportunity to provide feedback.

Founded in 1980, the Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease and other dementias through the advancement of research, and as the world's largest nonprofit funder of Alzheimer's research, the Association is committed to accelerating progress of new treatments, preventions and, ultimately, a cure. Through our funded projects and partnerships, we have been part of every major research advancement over the past 30 years.

No single organization can surmount a challenge as great as Alzheimer's. To help achieve our vision of a world without Alzheimer's, the Association partners with key government, industry and academic stakeholders in the global race to end Alzheimer's. We believe in the value of collaboration and work toward the day when we will have disease-modifying treatments, preventive strategies and gold-standard care for all people affected by Alzheimer's disease.

Promoting Patient and Caregiver Engagement in Drug Development

The Association applauds the Committee for including the Patient Focused Drug Development (PFDD; TITLE I: SUBTITLE A) provision in the discussion draft. The Association agrees that it is crucial to include the patient perspective in such areas as risks and benefits, targeted endpoints, and meaningful outcomes, and thus supports the enhancement of the PFDD program. With a disease like Alzheimer's, it is important to also include the perspective of care partners as well as the individual with the disease. The Association looks forward to working with the Food and Drug Administration (FDA) through the public comment period and at the public workshop on this important topic.

Identifying additional partnership opportunities with the private sector and facilitating collaborative efforts to enhance identification of risk factors and early biomarkers is a key action item in the *National Plan to Address Alzheimer's Disease* (National Plan). The surrogate endpoint qualification and utilization (TITLE I: SUBTITLE B) section not only establishes a predictable, transparent process for FDA's consideration and qualification of endpoints, but also allows FDA to use private-public partnerships to qualify other types of biomarkers. This initiative mirrors efforts by the Association that have been called upon by the National Plan.

Since 2005, the Association has partnered with the National Institute on Aging, the National Institute of Bioimaging and Bioengineering, the National Institute of Mental Health, the National Institute of Neurological Disorders

and Stroke, the National Institute of Nursing Research and the National Institute on Drug Abuse on the Alzheimer's Disease Neuroimaging Initiative (ADNI.) ADNI seeks to find more sensitive and accurate methods to detect Alzheimer's disease at earlier stages and mark its progress through biomarkers. Partnerships like ADNI have made significant inroads into this complex disease and the Association supports these efforts by the Committee.

Regulation of New Diagnostic and Medical Technology

In January 2013, the Association, along with other experts in the dementia care and research fields, had the opportunity to testify before the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on beta amyloid positron emission tomography (PET) imaging and its role in early and accurate diagnoses of Alzheimer's disease. The question at hand – amyloid PET scanning – was highly technical; unfortunately, MEDCAC members lacked a fundamental understanding of and sensitivity to dementia and the population affected by it. Panelists were forced to spend their limited time before MEDCAC providing a very basic education on the disease, leaving little opportunity to discuss the risks, benefits, and significance of the test. MEDCAC members lacked a rudimentary understanding of a disease prevalent and growing among Medicare beneficiaries.

The Association remains disappointed with the determination of Coverage with Evidence Development (CED) given the sufficient evidence and corresponding clear, scientific consensus recommendations provided to the Centers for Medicare and Medicaid Services (CMS) by the Association and the Society for Nuclear Medicine and Molecular Imaging (SNMMI) regarding appropriate, limited coverage, only in specific populations. The Association greatly appreciates efforts to reform Coverage with Evidence Development to ensure that seniors have access to innovative diagnostics at lower cost to Medicare beneficiaries (TITLE II: SUBTITLE H).

The Association supports the Committee's efforts to modernize the regulation of diagnostics (TITLE II: SUBTITLE J.) Alzheimer's disease is the most expensive disease in the United States, with costs estimated to skyrocket in the future. Beyond the economic costs are the emotional costs placed on the families and caregivers of those with the disease. While new diagnostic technologies are being developed, we still do not have a definitive methodology for diagnosing Alzheimer's. That is why it is vital that new regulations on diagnostics must include protections for patients and consumers. There must be strong scientific consensus behind new diagnostic modalities and that the results are reported to patients in the proper context (e.g., differences between increased risk factors and diagnosis).

Clinical Trial Modernization

The National Plan calls for the National Institutes of Health (NIH) to identify ways to compress the time between target identification and release of pharmacological treatments. There is evidence that a single Institutional Review Board (IRB) for multi-site studies can lead to enhanced protections for patients through increased accountability, a decrease in conflicts of interest, and improved efficiency through a refocusing of resources. These benefits plus the acceleration of the pace of research is particularly important to individuals affected by Alzheimer's disease and other dementias.

The Alzheimer's research community overwhelmingly supports the concept of a centralized IRB (TITLE III: SUBTITLE A), as have participants in several expert think tank and strategy meetings, including the 2012 Alzheimer's Disease Research Summit and meetings of the Advisory Council on Alzheimer's Research, Care, and Services.

Data Sharing

Establishing a 21st century data sharing framework for public research will help accelerate the development of new medical technologies and advance breakthroughs (TITLE II: SUBTITLE F/I/M). The Association has developed the Global Alzheimer's Association Interactive Network (GAAIN) to provide researchers around the globe with access to a vast repository of Alzheimer's research data. GAAIN is a global hub for Alzheimer's research data that allows researchers to search across multiple data sources instantly and contact these data partners directly for data.

GAAIN aggregates information about our partners' data and shares with researchers without infringing upon data partner data sharing policies and regulations. Data partners always remain in control of their data. It is the first global big data initiative in Alzheimer's disease research and serves as a benchmark for computational research in

other complex diseases. The Association supports efforts to facilitate data sharing and hopes the Committee will look to GAAIN as a successful example

21st Century Cures Consortium

The National Plan milestones require NIH in partnership with FDA and CMS maximize collaboration among federal agencies and CMS. The 21st Century Cures Consortium (TITLE II: SUBTITLE A) shares this goal by seeking to bring in the perspectives of industry, academia and patient groups. Input from patients and the broader community on research, clinical care and data sharing will provide a greater insight on the state of innovation and will lead to greater collaboration in the discovery and development of new treatments.

Incentivizing Investment in Drug Development

The Association recognizes the challenges that are faced by drug developers when addressing a disease as complex as Alzheimer's. The current incentive framework may not properly incentivize drug developers to research, develop and manufacture products for complex neurodegenerative diseases. The Association appreciates the recognition of this issue by the committee and hopes this will lead to a deeper discussion on ways to improve the framework to ensure these unmet needs are addressed.

The Association appreciates the steadfast support of the Committee and the great endeavor in which its members are engaged. We look forward to continuing to work with the Committee in order to address the Alzheimer's crisis and hope that the Association will be called upon for our expertise in this area. If you have any questions or need further information please contact Rachel Conant at rconant@alz.org or 202-638-7121.

Sincerely,

[redacted]

Robert Egge
Executive Vice President, Government Affairs

ALZHEIMER'S FOUNDATION OF AMERICA

Our mission is "to provide optimal care and services to individuals confronting dementia, and to their caregivers and families—through member organizations dedicated to improving quality of life."

February 9, 2015

The Honorable Fred Upton
Chairman
Energy & Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Congresswoman Diana DeGette
U.S. House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Congresswoman DeGette:

On behalf of the Alzheimer's Foundation of America (AFA), a national nonprofit organization that unites more than 1,900 member organizations nationwide with the goal of providing optimal care and services to individuals confronting dementia, and to their caregivers and families, I am writing to commend you and members of the House Energy and Commerce Committee for all your work in developing the 21st Century Cures Act. AFA also appreciates the transparency of the process and the opportunity for stakeholders to weigh-in with comments and recommendations.

As our nation faces the unprecedented public health crisis posed by Alzheimer's disease, AFA believes it is critical to advance efforts for development of therapy and prevention, and to do so in a fashion that accelerates the process while ensuring participant safety and drug efficacy. AFA applauds the Energy and Commerce Committee for recognizing the regulatory challenges posed by drug development in the Alzheimer's space and addressing them in innovative and creative ways.

The Centers for Disease Control and Prevention (CDC) ranks Alzheimer's disease the sixth leading cause of death in the US. A recent study, however, finds that deaths attributed to Alzheimer's disease are vastly underreported.[1] If accurately tracked, Alzheimer's disease is responsible for over 200,000 deaths in the US making it the third leading cause of death. Moreover, it is the only cause of death in the top ten with no cure or treatment to reverse or slow its progression. There has not been a new treatment for Alzheimer's disease in almost 15 years, and the treatments that are available today only provide temporary slowing of symptom progression.

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[1] See, Contribution of Alzheimer disease to mortality in the United States, James, Bryan Ph.D. et. al., Neurology (March 5, 2014) (www.neurology.org/content/early/2014/03/05/WNL.0000000000000240).

As part of a federal response, a national Alzheimer's plan[2] has been developed which calls for finding a cure or meaningful treatment for the disease by 2025. The innovative and creative approaches contained in the 21st Century Cares bill will help clear some obstacles and regulatory hurdles that currently block real progress on promising treatments and stifles drug development. Reform in this area is necessary to foster new drug development that will allow us to achieve the ultimate goal of the national Alzheimer's plan.

AFA supports the bill's emphasis on "Putting Patients First" and the active inclusion of persons with chronic disease, including those living with dementia and their family caregivers, at all points in the decision making process. A first step is using patient experience data to enhance a structured risk-benefit assessment framework, including genetic testing and genetic counselling. AFA also supports additional measures in the legislation which will provide for better use of surrogate endpoints, including advances in computerized neuro-cognitive and brain-disease analyses, expanded access to investigative treatments and modernization of the regulation of social media to facilitate responsible communication of medical and scientific developments.

In addition AFA supports proposals that will streamline the Food & Drug Administration's (FDA's) premarket review process, establish a new regulatory framework, enhance the efficiency of FDA review of combination products and encourage use of stream-lined statistical methodologies for clinical trials. AFA commends the Committee for including provisions to help young scientists, support projects that are high risk but could lead to breakthroughs, and require those receiving NIH grants to share their data. In addition, AFA supports providing additional resources to the BRAIN Initiative which has the potential of unlocking the mysteries of the brain, including dementia.

AFA, however, does have some concerns and offers the following recommendations to improve the legislation:

- Reform of Coverage with Evidence Development (CED) – AFA has several concerns with the current CED, including:
    - Slow pace of trial approval with a cumbersome and uncertain path to trial approval;
    - Potentially long CED periods without clear evidence goals;
    - Very limited coverage during the CED period;
    - No coverage while trial data are being analyzed; and
    - Unfunded federal requirements for trial operation.

AFA calls on the Committee to address these issues with the CED in the 21st Century Cures bill.

- 21st Century Chronic Disease Initiative Act – AFA has concerns that the proposed longitudinal study could shift resources away from promising research and divert focus from the overarching goal of the National Plan to Address Alzheimer's Disease to provide a cure or meaningful treatment by 2025. There are already existing longitudinal studies, moreover, that can provide similar data. A higher level analysis and monitoring of hypotheses that may explain Alzheimer's disease is needed to redirect the field to potentially successful directions.

- Telemedicine - AFA supports efforts, including those in the bill, to promote telehealth and remote patient monitoring. Yet, given the reluctance from the Centers for Medicare and Medicaid Services (CMS) to adopt such technology, we urge the Committee to consider an approach that gives the Department of Health and Human Service (HHS) authority to expand or constrict telehealth services according to their budget impact, but rests the power to approve Medicare beneficiaries' access to telehealth and remote patient monitoring in Congress. In addition, we urge the bill to include a proposals to create a Telehealth Advisory Committee to advise HHS and CMS on what services should be covered based on evidence of cost savings or cost neutrality.

[2] The National Alzheimer's Project Act (NAPA) (P.L. 111-375) was passed unanimously by both houses of Congress and signed by President Obama in January 2011, and calls for creation of a national strategic plan to address the rapidly escalating Alzheimer's crisis and to coordinate Alzheimer's disease efforts across the federal government.

ADDITIONAL RECOMMENDATIONS:

Early Detection and Memory Screening

AFA has long supported efforts to increase awareness of the importance and benefits of early detection of Alzheimer's disease and related dementias. Early identification of at-risk individuals provides multiple benefits to the person with Alzheimer's disease, the caregiver, the family and society. For the affected individual, identification of early-stage dementia allows a better understanding of and dialogue about the disease, early and appropriate use of beneficial treatments and social and behavioral interventions, planning for the future, and utilization of support services for themselves and their families. Early detection can also lead to a better understanding of Alzheimer's disease and provide a faster and more efficient path to prevention.

AFA **urges the Committee to include policy that promotes cognitive assessment and requires all dementia drug trials to collect data on computerized cognitive tests.** The time commitment from patients would be minimal, while the data collected would be invaluable in helping to increase our understanding of Alzheimer's disease and best methodologies to detect and track cognitive impairment.

Reforming 510(k) Process for Computerized Cognitive Assessment Tests

While promising drug therapies will have access to such fast tracking, it's unfortunate that diagnostic tools for Alzheimer's disease are not being cleared with the same urgency. To date, FDA has categorized such computer assessment tests as Class III "medical devices" requiring premarket submission and review. This premarket approval process can take over two years and cost millions of dollars. More importantly, lack of FDA clearance has delayed acceptance of several effective cognitive assessment tools which could delay a timely diagnosis of dementia.

Yet, several assessment tests have been widely and safely used by clinicians to help diagnose dementia and to assess its progression and severity. A test like the Mini Mental State Examination (MMSE, Folstein et al. 1975) is allowed, but not FDA cleared, despite being widely used in drug research trials. Much better assessment approaches are needed to replace this out-of-date 40 year old test, and such tests will only be developed in a conducive regulatory environment.

AFA urges making such widely used and clinically accepted cognitive assessment tests be subject to FDA's 510(k) approval process. This will allow for an expedited clearance process for proven computerized cognitive assessment tests. Under this process, moreover, the substantial equivalence determination for low risk devices is based primarily on descriptive information and a labeling review, while the decision for higher risk devices relies on performance data.

Support International Research Cooperation

There has been considerable movement in the worldwide effort to fight Alzheimer's disease. Since the G8 Summit held in London in late 2013, there has been a more coordinated international effort in combating dementia. The G-7 has committed to identifying a cure or a disease modifying therapy by 2025 and to increase funding for dementia research.[3] To this end, international policy makers have met at various legacy meetings throughout 2014 (with more scheduled in 2015, including a meeting in February at NIH). In addition, Dr. Dennis Gillings, consultant to the pharmaceutical industry and founder of a drug trial, has been appointed by the UK Prime Minister as the World Dementia Envoy.[4]

As a leader in Alzheimer's disease research, the US needs to continue its commitment to these international organizations. The sharing of research data, best practices and study results will speed drug development and help

[3] G8 Dementia Summit Declaration (issued Dec. 11, 2013) (www.gov.uk/government/publications/g8-dementia-summit-agreements/g8-dementia-summit-declaration).
[4] See, http://dementiachallenge.dh.gov.uk/2014/02/28/dennis-gillings-appointed-world-dementia-envoy/.

achieve the shared 2025 goal. **It is imperative, therefore, that the 21st Century Cures bill contains provisions that require a greater commitment to these international efforts** in the areas of sharing clinical research data and drug therapy development.

Clinical Trial Outreach

For Alzheimer's disease, one of the biggest obstacles to discovering a new treatment or prevention strategy is finding volunteers for studies to allow research to progress at the pace needed to develop more effective treatments. Education and outreach is especially needed, especially in minority communities where persons are more at risk but barriers to recruitment are high. New outreach methods and awareness campaigns are needed to address this need for clinical volunteers across all demographics.

To help facilitate this outreach, AFA **urges the 21st Century Cures bill to**:

- **Establish large-scale patient registries** to facilitate faster and less expensive clinical trial recruitment.
- Call on public and private sectors to work together to **address the unique circumstances of individuals with Alzheimer's disease and their ability to provide informed consent** for clinical trial participation.
- Encourage all new and ongoing federally-funded and industry-sponsored Alzheimer's disease clinical trials to **use the same Alzheimer's disease data standards developed by the Clinical Data Interchange Standards Consortium (CDISC) in order to facilitate data sharing** and review by the FDA.

AFA appreciates and supports efforts of the House Energy and Commerce Committee to take comprehensive look at what steps Congress and other policy makers can take to accelerate the pace of cures in the United States. We are grateful for the opportunity to make comments and hope to continue working with the Committee to promote legislative and regulatory policies that fosters drug development in the Alzheimer's disease space. Feel free to contact me or Eric Sokol, AFA's vice president of public policy, at esokol@alzfdn.org if you have questions or need further information.

Sincerely,

Charles Fuschillo, Jr.

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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February 18, 2015

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Joseph Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
2322A Rayburn House Office Building

The Honorable Diana DeGette
Committee on Energy and Commerce
2368 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Ranking Member Pallone, Chairman Pitts, Ranking Member Green and Representative DeGette:

The American Academy of Ophthalmology applauds the Energy and Commerce's efforts to help accelerate the discovery, development, and delivery of promising new treatments and cures for patients. The Academy is the world's largest association of eye physicians and surgeons, and more than 93 percent of practicing U.S. ophthalmologists are Academy members. We appreciate the opportunity to provide comments on the recently released draft legislation, "the 21st Century Cures Act," and we would welcome the opportunity to work with the Committee on this wide-ranging initiative.

Section 4241 – Treatment of Global Services Rule:

The American Academy of Ophthalmology greatly appreciates the inclusion of language to block implementation of the policy in the 2015 Final Medicare Physician Fee Schedule Rule to transition 10- and 90-day global period codes to 0-day global period codes beginning in 2017. As you know, these global codes include necessary services normally furnished by a surgeon before, during and after a surgical procedure. Despite the fact that the policy will affect 10-day global codes in 2017 and 90-day global codes in 2018, the Centers for Medicare and Medicaid Services (CMS) has not yet presented a methodology for making this transition.

The Academy believes that CMS's policy will be extremely detrimental to beneficiary care, increase administrative burdens and hinder ongoing efforts to reform the Medicare physician payment system. More specifically, the Academy is concerned that this policy has the potential to do the following:

- Detract from quality of care by potentially reducing the surgeon's ability to oversee and coordinate care;
- Undermine the current efforts to reform the Medicare physician payment system and repeal the sustainable growth rate formula;
- Place patients, particularly sicker patients, at risk for paying additional copayments which could discourage them from coming back for appropriate follow up care;
- Increase administrative burden on CMS as the American Medical Association estimates that eliminating the global package for procedures will result in 63 million additional claims per year; and
- Obstruct clinical registry data collection and quality improvements.

The Academy commends the Committee for recognizing the wide-ranging impact the CMS policy could have on physicians and their patients and including the language in section 4241 to prevent CMS from moving forward with its implementation. We strongly recommend that Congress take all necessary steps to prevent this detrimental policy from taking effect.

Section 2091 – Commission on Data Sharing for Research and Development:

The American Academy of Ophthalmology also greatly appreciates the Energy and Commerce Committee's recognition that clinical data registries, such as the Academy's IRIS™ Registry, will continue to play an important role in accelerating the discovery, development and delivery of cures for patients. We supports the inclusion of language in the 21st Century Cures Act to address challenges facing clinical data registries in order to enhance their ability to improve quality, patient outcomes, and advance faster cures for patients.

Section 2091 of the draft bill would establish a "Commission on Data Sharing for Research Development." While the Academy appreciates the intent of the commission, we have concerns with some of the commission's duties outlined in subsection (b)(2). We believe that these duties are duplicative of policies already in place, and these efforts would not be necessary, especially as they apply to Qualified Clinical Data Registries (QCDRs).

Registries qualified by CMS as a Qualified Clinical Data Registry are already required to have in place and execute a data validation strategy to ensure the accuracy and integrity of the data included in the registry. QCDRs must be in compliance with CMS-specified secure methods for data submission, with applicable privacy and security laws, and have in place a data privacy and security plan. QCDRs must also prove that they have in place mechanisms to ensure the transparency of their data, and QCDRs are subject to audits by CMS upon request. Therefore, we suggest that this subsection be removed, or that it be modified to clarify that the commission's duties and final products do not focus on QCDRs, and that any legislation resulting from the commission's work not apply to QCDRs.

Section 2092 – Recommendations for development and use of clinical data registries:

The Academy strongly believes that physician-led clinical data registries hold great potential to improve patient care. However, clinical data registries that are EHR-based are dependent upon the interoperability of health IT. Clinical data registries, such as the Academy's IRIS Registry, are capable

of integrating health information from a variety of data sources to be used by providers, researchers and other stakeholders in a meaningful way to improve the efficiency and quality of care provided by clinicians, and to improve outcomes for patients. For example, IRIS Registry's system-integration software program is designed to work with any EHR system, and to date, IRIS Registry has successfully integrated with 26 different EHR systems.

However, interoperability still exists as a challenge for clinical data registries. Section 2092 of the draft legislation appears to be an attempt to address this issue, requiring the Secretary to publish a set of recommendations related to the development and use of clinical data registries, including "recommendations for a set of standards that, if adopted by such registries, would allow for the bidirectional, interoperable exchange of information between the electronic health records of the reporting clinicians and such registries."

This language, however, does not adequately address the interoperability challenges facing clinical data registries. We believe that this language falls short because it places the responsibility of adopting standards on the registries rather than the EHRs. Even if registries adopt certain agreed upon standards, there still would not be any bidirectional, interoperable exchange of information between EHRs and registries because EHRs are not required to share information with registries. Ultimately, the interoperability challenges between clinical data registries and EHRs are not a result of a technology issue, such as lack of or failure to adopt certain standards. Instead, these challenges exist because there is no business case or incentive for EHR vendors to integrate or share data with registries. Currently, our registry is capable of working with any EHR, and there is no technology challenge preventing us from working with any EHR system. However, because EHRs are not required to work with registries, some choose not to, or some charge their physicians high "add on fees", because it isn't a priority.

The Academy believes that leveraging the Meaningful Use EHR Certification program would provide the incentive needed to encourage EHR vendors to work with and exchange data with clinical data registries. Therefore, the Academy suggests that this section be re-worded in a way that requires that any EHR that is certified by ONC comply with standards set by ONC that allow for the bidirectional, interoperable exchange of information between EHRs and clinical data registries. This would incentivize EHRs to open up and share their data with registries, because if they did not comply, they would lose their certification status, and the providers using their systems would be forced to find another system in order to succeed in the Meaningful Use program. Section 2181 is currently marked as a placeholder for interoperability language, and the Academy suggests that this section too could reflect these comments.

Section 2092 also asks the Secretary to make recommendations on how clinical registries may be developed and used to evaluate various care models, and as well as recommendations on how registries should be structured to facilitate the recording and reporting of post market data for the purposes of monitoring safety and efficacy of FDA-approved devices and drugs. This section also asks for recommendations on how registries can be used to promote preventive health benefits. The Academy strongly supports the provision in the 21st Century Cures Draft that requires the Secretary consult with national medical specialty societies in the development of such recommendations. Given that many clinical data registries are currently performing such functions, this consultation is critical in ensuring that the Secretary not make recommendations that would disrupt or cause to change path, the work already underway by many registries, delaying the advancement of cures facilitated through registries.

<u>Subtitle O – Accelerating Innovation in Medicine</u>

The Academy supports efforts to ensure that new, innovative technologies are available to patients as quickly as possible and applaud efforts to streamline and increase efficiencies in the drug and device

approval and coverage determination processes. While the Academy supports the goal of the AIM Act—getting innovative technologies to patients more quickly—there are some concerns about the current proposal.

Language included in the current proposal would allow a manufacturer to list their device on the "AIM list" for an indefinite period of time. The Academy is concerned that this could ultimately result in situations where a medical device is necessary for treatment of a particular patient, yet will be unaffordable (and therefore unavailable) for that patient without the means to self-pay for a product that would otherwise have been covered by Medicare or commercial insurance. If a manufacturer does not have a financial incentive to apply for Medicare coverage of a product, it is possible that certain treatments will only be available to the segment of the population with the means to afford to self-pay for the device, often at a premium. Given the potential effect on access to products that could result from the ability of a manufacturer to list its products on the "AIM list" in perpetuity, the Academy suggests that the Committee consider placing a cap on the length of time a product can opt-out of applying for Medicare coverage. Capping the length of the opt-out listing would help to strike a balance between getting innovative products quickly to market without significant administrative burdens, facilitating the immediate collection of clinical data on the safety and effectiveness of the device, and assuring that products proven to be beneficial to health of patients are eventually available all patients, not only those who can afford them.

Conclusion:

Again, the Academy applauds the Committee's efforts to spur innovation and accelerate the pace of cures in the United States. We appreciate the opportunity to submit recommendations on the draft 21st Century Cures Act. Please do not hesitate to contact me or Rebecca Hyder in the Academy's Washington office with any questions on the Academy's comments and recommendations. Rebecca can be reached at 202-737-6662 or rhyder@aaodc.org.

Sincerely,

[redacted]

Michael X. Repka, MD, MBA
Medical Director for Government Affairs
American Academy of Ophthalmology

American Academy of Pediatrics Comments on the 21st Century Cures Discussion Draft (January 26, 2015 at 5:26 pm)

February 13, 2015

The American Academy of Pediatrics (AAP), a non-profit professional organization of 62,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, welcomes this opportunity to provide comments on the 21st Century Cures Discussion Draft dated January 26, 2015 (5:26 pm).

The AAP commends Chairman Upton and Ranking Member DeGette for undertaking this year-long effort to explore ways in which we can accelerate the discovery, development, and delivery of promising new treatments and cures for patients. Children are often referred to as "therapeutic orphans" because the pace of development and discovery of treatments for children has not kept pace with that for adults.

The AAP is still analyzing the discussion draft and looks forward to reviewing the sections for which language is not yet available. When the complete language is available, we intend to provide the committee with a formal response to the discussion draft but, at the request of the committee, we offer the following initial comments.

Best Pharmaceuticals for Children Act/Pediatric Research Equity Act

The AAP is extremely grateful for the leadership of Chairman Upton and others in strengthening and making permanent the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) in the 2012 *Food and Drug Administration Safety and Innovation Act (FDASIA).* To date, BPCA and PREA have led to 538 drug label changes with new pediatric information and have resulted in roughly 1,000 trials involving children. The AAP worked closely with the Energy and Commerce Committee and other stakeholders to reach consensus on the changes that enabled BPCA and PREA to be made permanent and, in the end, that consensus received broad-reaching and strong support. AAP is encouraged by the efforts of the Food and Drug Administration (FDA) to implement these changes, something that is still underway. As a result of the consensus process of the Committee and the progress underway at FDA to implement the laws, the AAP is not seeking changes to BPCA and PREA in the 21st Century Cures discussion draft and as you continue working to refine the discussion draft, AAP would recommend that careful attention be paid to ways in which other provisions in the draft may directly or indirectly interact with the pediatric incentive and requirement. Given the tremendous success of BPCA and PREA for therapeutics for children, we would urge the Congress to take the approach of, first, do no harm, and second, look for ways to enhance pediatric research.

New Resources for the National Institutes of Health

Significant new resources for the National Institutes of Health (NIH) is perhaps the single most important commitment we can make to improving cures for our nation's children. In recent years, the Budget Control Act of 2011 has precipitated a substantial decline in pediatric research

funding when controlling for inflation. The recent erosion of purchasing power at NIH, particularly after the large funding increases of the previous decade, has had a serious impact on research and research infrastructure. NIH funding has become unstable and unpredictable, creating an unsustainable funding climate for research. Across the institutes and centers of NIH, basic and translational pediatric research is being conducted to lay the groundwork that will ultimately result in future treatments for children. We must increase investments in this research and we ask that the 21st Century Cures Initiative work to significantly increase funding for the NIH. This funding is not only necessary for continuing important science, but also for supporting the training of the next generation of researchers. NIH grant mechanisms that support the training of young scientists, such as the T32 mechanism, are crucial and need sustained support.

Inclusion of Children in NIH Research

We strongly urge the committee to include language in the legislation to improve the tracking of pediatric research at the NIH. Since 1997, there has been a requirement that children must be included in research supported by the NIH unless there is scientific reason not to. This important policy helps to ensure that children also benefit from research advances relevant to them. Unfortunately, the NIH collects no systematic data to monitor its success in implementing this important provision. Similar inclusion policies exist for women and minorities, but the NIH tracks the numbers of women and minorities actually included in studies and does not do so for children. The NIH should be required to conduct systematic tracking of the ages of children included in the studies it supports to ensure that children are not inappropriately excluded from studies that could benefit them.

Support for Developing the Next Generation of Pediatric Pharmacologists

It is also vital that we invest in the development of young researchers who will conduct the next generation of research studies to develop new cures. This is particularly important in pediatrics because there is a dearth of highly qualified clinical pharmacologists trained specifically to do studies in children. Pediatric drug studies require specialized expertise because of their unique challenges. New and expanded financial incentives such as loan repayment for pediatric pharmacologists are needed to continue to develop this important workforce.

Title V, Subtitle D, Section 5067 (Humanitarian Device Exemption Application to In Vitro Diagnostics)

The AAP has worked for more than a decade to advance pediatric medical devices. Those efforts resulted in the enactment of the bipartisan *Pediatric Medical Device Safety and Improvement* Act in 2007 which was reauthorized in FDASIA in 2012. That law sought to incentivize device manufacturers of Humanitarian Device Exemption (HDE) devices by lifting the profit cap only for those devices intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients. The HDE pathway was created by congress to be way for devices for smaller market populations (affecting 4,000 or fewer patients) to come to market and, unlike a premarket application, devices only need show a probable benefit rather than the higher effectiveness standard. The pediatric profit incentive passed in 2007 had a sizeable impact on the number of pediatric Humanitarian Use Device designations sought by manufacturers, the precursor step to

seeking HDE approval. The impact was so great, that manufacturers sought to expand the profit for all markets in 2012.

While the 4,000 patient number has been the subject of much debate, there are insufficient data to inform an alternative number. The language in this section is highly problematic because it would have the effect of allowing any device that "affects more than 4,000 individuals" to be approved as an HDE so long as the manufacturer could show that the severity of the disease or condition is such that "the public health requires a greater availability of the device to treat or diagnose such patients" and "no satisfactory alternative is available for such treatment or diagnosis." We read this provision to compel FDA to act on any device under the HDE statute without the manufacturer showing adequate evidence of effectiveness and without regard to incidence of the disease of condition for which the device is intended to treat or diagnose.

We are unclear whether that was the intent of the provision but we would note that, despite our best efforts, medical device innovation for children continues to lag as much as 5 to 10 years behind that for adults so it is conceivable the most, if not all, pediatric medical devices could meet the standard in the proposal. While AAP is eager to work with congress and other stakeholders on ways to strengthen the HDE pathway in order that more pediatric devices can be approved by FDA and paid for by Medicaid and other private payers, AAP cannot support a lower approval standard for children. We look forward to working with you on the language in this proposal.

Title I, Subtitle N, Section 1261 (Orphan Product Extensions Now)

The AAP strongly supports increasing therapeutic options for children with rare diseases. Since half of all rare diseases have their origins in childhood and the market factors that affect pediatric product development are in many ways even more challenging for rare pediatric conditions, more can and should be done to develop new, on-label therapeutic options for pediatric rare diseases. Careful consideration should be paid to how any new incentive for rare diseases might interact or affect the existing pediatric incentive under BPCA. For instance, under BPCA, FDA issues a written request to a product sponsor which includes the studies and indications FDA would like completed. Written requests can include a rare disease indication. Acceptance of a written request is completely voluntary by a product sponsor. Upon fulfillment of the written request by a sponsor and a determination by FDA to grant exclusivity, sponsors receive an additional 6 months of exclusivity which is tied to the active moiety of the molecule. This can make it a highly powerful incentive but it means pediatric exclusivity can only awarded once since it applies to all forms and indications of the drugs.

A strength of BPCA is that while a product sponsor can initiate the ultimate issuance of a written request by submitting a Proposed Pediatric Study Request, FDA ultimately decides what goes into the written request and what studies and indication(s) the sponsor needs to pursue based on what would be maximally beneficial for pediatric patients in order to receive 6 months of exclusivity. This process is important because it balances the needs of pediatric patients with the cost of exclusivity to payers including federal programs like Medicare. The standard in the proposal is FDA approval of an application or supplemental application for a new indication for use of a drug to prevent, diagnose, or treat a rare disease or condition. Unlike under BPCA, the

language does not give FDA the ability to issue a written request (or something akin to a written request) in order to receive 6 months of exclusivity.

As the committee looks at ways to increase therapeutic options for children with rare diseases by increasing FDA-approved pediatric rare disease indications, AAP would note that orphan drugs are currently exempt from the premarket requirement under PREA. To date, PREA has resulted in hundreds of new FDA-approved pediatric indications.

Title III, Subtitle D, Section 3041 (Pediatric Research Network Improvement)

This section would require that the National Institutes of Health implement the National Pediatric Research Network Act. To date, no appropriations have been made available for this program and the discussion draft also does not offer any new funding for this program. Mandating the implementation of this Act without new funding would likely require the National Institute of Child Health and Human Development (NICHD) to shut down existing networks.

Title I, Subtitle M, Section 1241 (New Therapeutic Entities)

This section does not specify whether the six months of pediatric exclusivity offered under the Best Pharmaceuticals for Children Act (BPCA) would be additive on top of the up to 24-month extension offered in this section. If the committee chooses to move forward with this proposal, we would ask that the language be explicit that any new exclusivity not run concurrent with pediatric exclusivity in such a way that would negate the value of the incentive offered under BPCA.

It is not clear from the intent of the provision whether assessments conducted under PREA would be eligible for the extended exclusivity period. If that is not the intent, AAP would recommend clarifying language be added. If it is the intent, AAP would be interested in understanding the benefit of providing a new incentive for something sponsors would be required to do under current law. It is also worth noting that FDA can and does issue written requests under BPCA for PREA assessments so the possibility of a 6-month incentive for pediatric studies already exists under current law.

Title I, Subtitle D, Sections 1061-1062 (Antibiotic Drug Development)

The AAP has endorsed the Antibiotic Development to Advance Patient Treatment (ADAPT) Act and is supportive of the ADAPT Act moving forward in the legislative process.

Other Provisions

Although not included in the discussion draft, AAP would like to reiterate its support for the proposal submitted by the Coalition to Advance Maternal Therapeutics to create an Interagency Task Force on Research in Pregnant and Breastfeeding Women as well as a report by FDA on approved new drug applications with information on pregnancy and lactation. We believe these proposals will help enable women to manage chronic illness or health issues that arise during pregnancy in the safest possible manner, make informed decisions about the use of medications in the perinatal period, and meet their breastfeeding intentions, thereby improving health

outcomes for mother and child. As work continues on the discussion draft, AAP hopes these proposals can be included. We have attached the Coalition's letter for your reference.

The AAP greatly appreciates this opportunity to provide comments on the 21st Century Cures discussion draft and we look forward to being of assistance to the Committee in the future. Should you have any questions, please contact Tamar Magarik Haro (tharo@aap.org) or James Baumberger (jbaumberger@aap.org) in AAP's Washington, DC office at (202) 347-8600.

February 9, 2015

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
House Energy & Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

The Honorable Diana DeGette
2368 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Ranking Member Pallone, Representative DeGette and Members of the Energy and Commerce Committee,

On behalf of the undersigned organizations, we are writing to urge you to include language in the 21st Century Cures Initiative legislation that would create an interagency task force to advance research in pregnant and breastfeeding women. Additionally, we encourage you to create a mechanism by which the U.S. Food & Drug Administration (FDA) will report information to Congress on the data it has on this subject.

Each year, almost four million women in the United States give birth, and 75% of them breastfeed their infants[12]. There are 73.7 million women of childbearing age in the U.S[3]. Nearly all of these women will take a medication or receive a vaccine during pregnancy, but little is known about the effect of most drugs on a pregnant woman or her child, or the ways in which pregnancy may alter the uptake, metabolism and effect of medication. This gap in understanding has become increasingly problematic as more women with chronic disease become pregnant, requiring medications to manage chronic conditions throughout pregnancy. While the federal LactMed database collects and distributes the available information on drug levels in human milk, significant gaps still remain on the impact of drugs on breastfeeding women and their children.

The lack of robust information on the safety and efficacy of many drugs across the continuum from pregnancy through breastfeeding is due in part to the fact that FDA does not require drugs to be tested among pregnant or lactating mothers[4]. In fact, the vast majority of drug trials exclude this population. Without reliable data, women who are pregnant or nursing may decide to stop taking necessary medications, increasing risk for both mother and child. In other cases, women may choose not to initiate breastfeeding or may wean earlier than desired because they lack information about the extent of drug transfer into human milk, the potential impacts of the drug on milk production, and the impact of exposure on the infant. Even when drug safety data is available, there is usually limited data about how the changes of pregnancy and breastfeeding affect the proper dosage.

The goals of the 21st Century Cures Initiative to accelerate research and development, and improve the continuum from basic science to healthcare delivery, would be greatly advanced by including initiatives aimed at this key population. Two key provisions represent valuable and effective first steps to advancing research during pregnancy and breastfeeding:

1. **The creation of an interagency task force to advance research in pregnancy and lactation**. This would ensure communication among and between federal agencies and other key stakeholders. Such a task force would bring together federal agencies and stakeholders that conduct research and collect data on medications during pregnancy and breastfeeding.
2. **An annual report from FDA on approved new drug applications with information on pregnancy and lactation.** It is vital for Congress and stakeholders to understand what information is currently being collected by FDA in order to assess gaps, opportunities and needs.

Our organizations have come together to support progress toward the inclusion of pregnant and breastfeeding women in clinical trials, so that consumers and health care professionals have the most up-to-date and accurate information on the safety and efficacy of drugs that women are prescribed while pregnant or breastfeeding. We strongly urge you to include these two important provisions in the 21st Century Cures Initiative legislation, given their impact on such a large population. The better information and data we have on the effects of medications during pregnancy and breastfeeding, the healthier our mothers and babies will be. Please do not hesitate to contact Rachel Gandell with the American Congress of Obstetricians and Gynecologists at rgandell@acog.org, Katie Schubert with the Society for Maternal-Fetal Medicine at kschubert@dc-crd.com, or James Gelfand with the March of Dimes at jgelfand@marchofdimes.org should you have any questions.

Sincerely,

American Academy of Pediatrics
American Congress of Obstetricians and Gynecologists
March of Dimes
Society for Maternal-Fetal Medicine

[1] Martin JA, et al. "Births: Final data for 2013." *National vital statistics reports*; 64 .1. (2015).
[2] McDowell, et al. "Breastfeeding in the United States: findings from the national health and nutrition examination surveys, 1999-2006". *US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics*, 2008.
[3] Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties, and Puerto Rico Commonwealth and Municipios: April 1, 2010 to July 1, 2013 Source: U.S. Census Bureau, Population Division. Release Date: June 2014
[4] U.S. Food and Drug Administration, "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling," 2014

American Association of Colleges of Nursing

February 13, 2015

The Honorable Fred Upton
Chairman, House Energy and Commerce
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

As the national voice for baccalaureate and graduate nursing education, the American Association of Colleges of Nursing's (AACN) membership is comprised of over 760 schools of nursing across all 50 states and the District of Columbia. AACN members educate over 425,000 nursing students by utilizing the expertise of nearly 17,000 faculty members. Moreover, AACN institutions graduate and employ many of the profession's finest leaders who are working to improve America's health through advancements in education, research, and clinical practice.

Given our mission and the members we represent, AACN commends the vision and intent behind the 21st Century Cures discussion document. Specifically, we would like to comment on the components of the draft that relate to young and emerging scientists, clinical research, as well as provider neutral language to ensure all professionals are included in these solutions.

Title II Building the Foundation for 21st Century Medicine Including Helping Young Scientists
Subtitle A (Section 2001) - 21st Century Cure Consortium Act
Subtitle N (Section 2241) - 21st Century Chronic Disease Initiative Act

AACN applauds the goals of Title II as the provisions are directed to leverage advances in science, technology, and research. Our deans, faculty, and doctoral student members are active participants in the scientific inquiry that improves health care in this country. For decades, nursing science's impact on improving healthcare delivery has proven far-reaching. Often working collaboratively with physicians and other researchers, nurse scientists are vital in setting the national research agenda. The role of nursing science in healthcare innovation is more critical than ever and directly helps to "aid in the discovery, development, and delivery of the next generation of patient-centered solutions here in the United States." We appreciate the neutral language included in *Subtitle A (Section 2001) - 21st Century Cure Consortium Act,* which would include all types of academic researchers as potential representatives appointed to the consortium. The nursing voice could substantially contribute to these dialogues.

Similarly, AACN applauds neutral language to include all academic researchers in *Subtitle N (Section 2241) 21st Century Chronic Disease Initiative Act.* Nurse researchers make vital contributions through their investigations on ways to prevent, manage, and treat those with chronic illnesses and support their families.

Subtitle K (Section 2181) – Interoperability
Subtitle Q (Section 2301) – Precision Medicine

We look forward to seeing more detailed language regarding interoperability. Since 2009, AACN and many colleagues in the nursing community have supported the federal government's push

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towards a nationwide interoperable health information infrastructure that protects the privacy rights of individuals, improves safety and reliability, all while ensuring cost-effective and coordinated care.[i] This includes: supporting effective collection of standardized, evidence-based performance information that will accurately measure quality and enable transition to a value-based payment system; ensuring that Advanced Practice Registered Nurses (APRNs) and Registered Nurses (RNs) are integral leaders and participants in the design, development, implementation, and evaluation of health information technology systems; and ensure that equitable resources, such as incentive payments for implementation, are available and extended to all healthcare professionals, including APRNs and RNs.[i]

Similarly, we look forward to seeing specific language on the precision medicine placeholder. Patient-centered care targeted at the individual should be core to all treatments. Nursing insights are critical to these discussions and discoveries.

Subtitle O (Section 2261-2262) - Helping Young Emerging Scientists

We commend the proposed investments for young emerging scientists. According to AACN, in the last academic year there were 5,145 nursing students in research-focused doctoral programs.[ii] These terminal degree programs prepare nursing students to pursue intellectual inquiry and conduct independent research for the purpose of extending knowledge. During their programs, they are prepared to drive change and innovation that will improve health nationally and globally. Like other scientists, competition is intense after these nurse researchers graduate and prepare programs of research as principle investigators.

We believe it is important that emerging scientists with strong research questions have opportunities to build long careers as investigators. Section 2261, clearly denotes that these funds would be available to all institutes and centers, which includes the National Institute of Nursing Research (NINR, National Institutes of Health [NIH]). Research funded at NINR helps to integrate biology and behavior as well as design new technology and tools. NINR's research fosters advances in nursing practice, improves patient care, works to eliminate health disparities, and attracts new students to the profession. Support for emerging scientists is an investment in the scientific endeavors that will generate new knowledge for better health. AACN is a strong supporter of all institutes and centers at the NIH and hopes that the funding for the agency is sustainable to make the innovations necessary for improving health and quality of life.

Title III- Modernizing Clinical Trails

Subtitle A (Section 3001) - Clinical Research Modernization Act

AACN recognizes the need to streamline the institutional review board process when a study is multi-site with the intent that this will decrease duplication and delays. This could expedite approval processes, decrease administrative burden, and standardize procedures. Whatever efforts are made to do so must not be at the cost of the long negotiated agreements and relationships between sites and foundational understanding of the clinical trials. Clear and structured guidance must be available to protect those involved in the study.

Title IV Subtitle I Telemedicine

Real discussions on access to health cannot occur in the 21st century without thoughtful discussion on the use of technology to aid in the process. The use of telehealth services is increasing and the

research from multiple industries, (i.e. nursing, medicine) has demonstrated their value. A wide range of healthcare providers, such as APRNs and RNs, are engaged in telehealth services. Therefore, we firmly believe the provision should be titled "telehealth" as opposed to telemedicine, to reflect common usage, and to remove any impression that the section refers only to physicians.

Provider Neutral Language
Consistent Use of Provide-Neutral Language

The 21st Century Cures discussion draft is expansive and wide-reaching. In the spirit of full inclusivity and the role that all providers have in improving healthcare delivery, AACN acknowledges and endorses the important use of provider-neutral language throughout. In some instances, however, the language uses the term "physician" when it should also include APRNs and other providers. This change would support and reinforce the reality that the contributions of all providers maximize the patient's experience and quality of care.

We request that the following instances of "physician" be corrected to "physician or other healthcare providers," including but not limited to: page 22 line 1; page 84 line 6; page 85 line 11; page 145 lines 12, 13 and 15; page 164 line 2; page 189 line 11; page 315 line 4; page 321 lines 10 and 16; and page 371 line 7.

Again, we commend the movement that has been made on the themes and goals of the 21st Century Cures initiative. We look forward to working with you and your colleagues as the final legislation is drafted. If AACN can be of any assistance, please do not hesitate to contact Dr. Suzanne Miyamoto, AACN's Senior Director of Government Affairs and Health Policy, at smiyamoto@aacn.nche.edu or 202-463-693, ext. 247.

Sincerely,

Deborah E. Trautman, PhD, RN
Chief Executive Officer

CC:
Ranking Member, Energy and Commerce Committee, Frank Pallone
Chairman, Energy and Commerce Health Subcommittee, Joseph Pitts
Ranking Member, Energy and Commerce Health Subcommittee, Gene Green
Representative Cathy McMorris Rodgers
Representative Michael C. Burgess
Representative Andy Harris
Representative Diana DeGette

[i] The Nursing Community (2009). *Commitment to Quality Health Reform: A Consensus Statement from the Nursing Community*. Retrieved from http://media.wix.com/ugd/148923_1ea66806aaf416fcab36e6752947415c.pdf.
[ii] American Association of Colleges of Nursing. (2014). *2013-2014 Enrollment and Graduations in Baccalaureate and Graduate Programs in Nursing*. Washington, DC.

February 12, 2015

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Upton:

The American Academy of Dermatology Association (Academy), which represents more than 13,500 dermatologists nationwide welcomes the opportunity to provide feedback on the House Energy & Commerce Committee's January 27, 2015, 21st Century Cures discussion document. We applaud your continued leadership in seeking stakeholder input on ways the U.S. can facilitate accelerated discovery, development, and delivery of biomedical innovations.

Title I – Putting Patients First by Incorporating Their Perspectives into the Regulatory Process and Addressing Unmet Needs

Subtitle A: Patient Focused Drug Development

The Academy *supports* the provision authored by Health Subcommittee Chairman Joe Pitts (R-PA) and Rep. Cathy McMorris Rodgers (R-WA) that uses patient data to inform the decision making process for drug development. The Academy thanks Members of the Committee for recognizing that the patient must be at the center of the medical innovation ecosystem and appreciates the Committee's commitment to ensuring that the patient voice plays a larger role in the research and development of new innovative therapies. Every day, our patients must cope with their disease while hoping for a treatment that will lessen their suffering. Including the patient perspective on issues such as quality of life, burden of the disease and the acceptable risks and benefits of a treatment will allow the Secretary to understand the risks a patient will tolerate in order to find some relief, and identify outcomes that are important to them in the treatment of their disease.

Subtitle C: Approval of Breakthrough Therapies

The Academy *supports* the provision authored by Rep. Michael Burgess, MD (R-TX) that will encourage innovation while ensuring patient safety is of paramount concern. The Academy notes that the FDA's breakthrough designation allows the agency to expedite the review and approval of life-changing or life-saving treatments. The Academy is encouraged to see that this provision include requirements that will ensure that evidence used to support this breakthrough designation will require data to show early clinical safety and effectiveness and gives the Secretary the authority to withdraw approval of a breakthrough designated drugs under certain conditions.

Subtitle E: Priority Review for Breakthrough Devices

The Academy *supports* the provision authored by Health Subcommittee Chairman Joe Pitts (R-PA) that provides authority to the FDA to designate breakthrough

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devices. The health care community has seen tremendous advances through the pharmaceutical breakthrough designation. This designation has allowed for the approval of life-changing treatments.

Subtitle J: Streamlined Data Review

The Academy *supports* the provision authored by Rep. Michael Burgess, MD (R-TX) regarding the use of streamlined data summaries for new indications or as a supplement to data already submitted with a drug application. The Academy recognizes the need for a streamline data reporting structure to allow for efficient reviews and approvals of new indication for treatments.

Subtitle K: Cures Acceleration Network

The Academy *supports* this provision, which would provide the National Center for Advancing Translational Science (NCATS) with more flexibility in obtaining and advancing R&D and authorizes additional funds for research on new uses for drugs whose patents have expired. The Academy supports this initiative, which could improve patient's access to treatments through discovery and new indications for existing treatments.

Title II – Building the Foundation for 21st Century Medicine, Including Helping Young Scientists

Subtitle B: Medical Product Innovation Advisory Commission

The Academy *notes* that the proposed Medical Product Innovation Advisory Commission, as discussed in Subtitle B, will provide recommendations on ensuring that policies will continue to promote innovation and acceleration of the discovery and delivery of needed treatments. The Academy appreciates that physicians are to be included in the roster of the proposed Commission. We *urge the Committee* to ensure that participating physicians represent all aspects of clinical care, including both academic and independent practice, to ensure a comprehensive perspective in advancing innovative treatments.

Subtitle F: Building a 21st Century Data Sharing Framework

The Academy *notes* the Committee's insertion of language authored by Rep. Morgan Griffith (R-VA), Rep. Leonard Lance (R-NJ), and Rep. Larry Bucshon, MD (R-IN) affecting the development and operation of clinical data registries, and appreciates the authors' efforts to improve access and use of these registries. The Academy, through the Physician Clinical Registry Coalition, will provide the Committee a more detailed analysis and suggested revisions to this provision.

Subtitle G: Utilizing Real World Evidence

The Academy *supports* the provision authored by Rep. Michael Burgess, MD (R-TX) regarding the use of real-world data to be included in post-approval studies or to support a new treatment that will promote patient access and adherence. Patient adherence is critical to ensure treatment and possible cure of a disease. Real world date, including usage, will provide a better understanding of how patients actually use the treatment. This information is vital for prescribers as they consider all treatment options.

Subtitle H: Coverage with Evidence Development

The Academy *supports* the inclusion of language authored by Rep. John Shimkus (R-IL) that would codify Medicare coverage of items or services that are the subject of a clinical trial for trial participants.

Subtitle K: Interoperability

The Academy *notes* the Committee's placeholder to later insert language addressing interoperability; the Academy commends to your attention the attached January 26, 2015 letter sent to you and Rep. Diana DeGette by 14 physician specialties that *requests* the Committee "mandate that ONC require EHRs certified for Meaningful Use to be capable of integrating with clinical data registries for quality improvement purposes," and "mandate that ONC facilitate the sharing of data elements defined by medical specialties to help inform EHRs as to what data elements to collect."

Subtitle O: Helping Young Emerging Scientists

The Academy *notes* the inclusion of this provision authored by Rep. Andy Harris, MD (R-MD) that would require that NIH tap funds be distributed to emerging investigators and for the NIH Director to report on the steps being taken by the agency to stem the decline of investigators under age 40. The Academy *supports* policy efforts to revitalize the pipeline of young scientists, and *urges the Committee* to authorize funding to allow appropriators to adequately fund this initiative.

Subtitle P: Fostering High Risk, High-Reward Science

The Academy *notes* the inclusion of this provision authored by Rep. Andy Harris, MD (R-MD) that would require the directors of each NIH institute to set aside funds to support high-risk projects that address major challenges and have the potential to lead to breakthroughs. The Academy *supports* policy initiatives that incentivize federal investment in high risk, high reward research projects. However, the Academy urges the Committee to authorize adequate funding for this type of research so it does not divert funds from other important research. The Academy supports the elimination of sequestration on biomedical research funding.

Title IV – Accelerating the Discovery, Development, and Delivery Cycle and Continuing 21st Century Innovation at NIH, FDA, CDC, and CMS

Subtitle A: Sec. 4007- Additional Funding for the NIH Common Fund

The Academy *supports* the inclusion of this provision, which authorizes additional funding for the NIH Common Fund. Research is a long-term investment. Short-sighted budget cuts have a direct impact on current and future research projects, weaken economic development, and will harm our patients' access to lifesaving treatments and cures.

Subtitle H: Local and National Coverage Decision Reforms

The Academy *supports* the inclusion of Health Subcommittee Vice Chair Brett Guthrie's (R-KY) provision that would require opportunities for the public to provide input in Medicare's local coverage determination (LCD) process, and would call for Medicare Administrative Contractors

to respond to public comments and include the evidence they used to make their determinations.

Subtitle I: Telemedicine

The Academy *notes* the inclusion of language authored by Health Subcommittee Chairman Joe Pitts (R-PA), Full Committee Ranking Member Frank Pallone (D-NJ), Rep. Gregg Harper (R-MS), Rep. Doris Matsui (D-CA), Rep. Bill Johnson (R-OH), Rep. Peter Welch (D-VT), Rep. Greg Walden (R-OR), and Rep. Bob Latta (R-OH) to improve access to telemedicine services. The Academy commends your attention to the attached feedback that was provided to the Telemedicine Working Group on January 26, 2015 that *requests the Committee* include Standards of Care language; utilize the term "telemedicine" in lieu of "telehealth;" direct the Secretary of HHS to utilize the AMA-CPT Editorial Panel for proper CPT code development; direct the Secretary to utilize the AMA Relative Value Update Committee process for the subsequent valuation of codes; support the Federation of State Medical Boards (FSMB) "Interstate Medical Licensure Compact," which will preserve the authority of state medical boards and allow physicians greater flexibility in practicing across state lines (the Academy believes a physician should be licensed by, or under the jurisdiction of, the medical board of the state where the patient is located); and provide clarity through legislative language that those providing telemedicine services practice commensurate with their licensure and/or experience and maintain the same criteria require for all face-to-face visits.

Subtitle K: Lowering Medicare Patients OOP Costs

The Academy *supports* the inclusion of language authored by Rep. Gus Bilirakis (R-FL) that would provide Medicare beneficiaries with information on the costs of covered items and services, as well as information on the providers who offer those items and services. The Academy believes, *however*, that it is essential that patients have access to accurate and up-to-date directories when they are enrolling in a plan and attempting to identify a physician to provide needed care. Having a standardized form that would allow CMS, or the appropriate regulator, to evaluate physician data provided by plans would assist the appropriate entity evaluate data accuracy and could also assist plans in updating their data in a more timely manner.

Subtitle L: Global Surgery Services Rule

The Academy *supports* the inclusion of language that would prevent implementation of CMS' 2015 Medicare Physician Fee Schedule Rule that would transition the 10 and 90 day global surgery codes to 0 day global surgery codes in 2017 and 2018, respectively. The Academy commends your attention to the attached December 2, 2014 letter to House and Senate leadership from 29 physician organizations *respectfully urging Congress* to take action to prevent this policy being implemented by CMS. The Academy, in coordination with our physician organization partners, offers to work with the Committee in fine-tuning legislative language that will ultimately achieve this goal.

Subtitle M: Providers Consolidation and Medicare Payments Examined Through Evaluation

The Academy *notes* the inclusion of language authored by Rep. Michael Burgess, MD (R-TX) that would require the HHS Secretary to evaluate and seek public comment on how certain changes to Medicare payment systems would affect provider consolidation. It is not clear, *however*, whether this provision would examine issues related to quality of care and patient cost

as a result of provider consolidation. Consequently, the Academy does not offer an opinion on this provision at this time.

Subtitle Q: Ensuring Local Medicare Administrative Contractors Evaluate Data Related to Category III Codes

The Academy *notes* the inclusion of the provision that would require Medicare Administrative Contractors to evaluate "all data" in developing a determination on Category III Codes. While the Academy supports the rigorous evaluation of data to inform coverage determinations, it would need a clear definition of "all data" before offering an opinion on the provision.

Subtitle S: Continuing Medical Education Sunshine Exemption

The Academy *supports* inclusion of the Continuing Medical Education Sunshine Exemption based on legislation (H.R. 293) introduced by Rep. Michael Burgess, MD (R-TX) and Rep. Peter DeFazio (D-OR) that would provide reporting relief imposed by CMS that discourages distribution of medical textbooks and peer-reviewed journals, and access to independent certified and/or accredited CME.

Title V – Modernizing Medical Product Regulation

Subtitle A: Manufacturing Incentives

The Academy is concerned about the rising cost of drugs, specifically the increasing cost of generic drugs. Generic drugs allow patient access to affordable, safe, and effective treatments. Without these medications, patients are faced with excessive out-of-pocket costs that may prevent them from staying on a treatment course and jeopardizing their health. Therefore, the Academy *supports* any efforts to incentivize and promote competition of generic drugs while maintaining patient safety such as the provision authored by Health Subcommittee Vice Chair Brett Guthrie (R-KY). This competition will allow for affordable and effective generics to be more readily available to our patients.

Other

The Academy urges the Committee to include the "Patients' Access to Treatments Act" (PATA, H.R. 460, 113th Congress) to the 21st Century Cures bill. PATA would limit cost-sharing requirements applicable to drugs in a non-preferred brand drug tier. A recent study found that 1 in ten American adults do not take prescribed medications due to cost *(Source: NCHS Data Brief: Strategies Used by Adults to Reduce their Prescription Costs, United States, 2013. January 2015).* The Academy commends your attention to the attached February 3, 2015 letter sent to you by 25 physician and patient organizations requesting the Committee include this bill in the final package.

To ensure that the research being supported today yields the breakthroughs of tomorrow, sustained funding is critical to achieving long-term and permanent treatments and cures. In recent years, budget cuts and fiscal pressures have had a direct impact on current and future research projects, potentially limiting our patients' access to life-saving treatments and cures in the future. And while increasing funding would best serve our nation's research infrastructure, it is also vital that efforts be focused on breaking down outdated and redundant regulatory

burdens, including, but not limited to, streamlining unnecessarily overly burdensome regulations in clinical trials that do not contribute to patient safety.

Thank you again for taking on this important task of modernizing health care policy intended to help the U.S. remain the leader in the field of biomedical innovation. We look forward to working with you in the coming months as the Committee fleshes out this legislative proposal. If you have any questions or if we can provide any additional information, please contact Christine O'Connor, the Academy's Associate Director, Congressional Policy, at coconnor@aad.org or (202) 609-6330, or Niva Murray, the Academy's Manager, Congressional Policy, at nmurray@aad.org or (202) 712-2608.

Sincerely,

[redacted]

Brett M. Coldiron, MD, FAAD
President, American Academy of Dermatology Association

February 10, 2015

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2125 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

RE: APRN Groups Express Support and Recommendations for the 21st Century Discussion Document

Dear Chairman Upton:

On behalf of the American Association of Nurse Practitioners (AANP), the largest full service professional organization representing the 205,000 nurse practitioners (NPs) across the country, we thank the Energy and Commerce Committee for their work on the 21st Century Cures Act. This draft legislation takes a thoughtful approach to improving the American health care system for discovery, development and delivery of 21st century cures. We would like to provide comment regarding the impact that sections of this draft legislation have on nurse practitioners and their patients.

Nurse practitioners have been providing primary, acute, and specialty care for half a century, and are rapidly becoming the health care provider of choice for millions of Americans. According to our most recent survey data, more than 900 million visits were made to NPs in 2012, a number we anticipate will continue to grow in the coming years. Nurse practitioners provide care in nearly every health care setting including clinics, hospitals, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), nursing homes, schools, colleges, retail clinics, public health departments, nurse managed clinics and homeless clinics. It is important to remember that in many of these settings nurse practitioners are the lead onsite provider. In addition to diagnosing and treating acute and chronic illnesses, nurse practitioners emphasize health promotion and disease prevention in the care of their patients. Daily practice includes: assessment, ordering, performing, supervising and interpreting diagnostic and laboratory tests, making diagnoses, initiating and managing treatment including prescribing medication (as well as non-pharmacologic treatments), coordination of care, counseling, and educating patients, their families and communities.

Additionally our data shows that the vast majority of nurse practitioners are primary care providers. Eighty-eight percent are educationally prepared to be primary care providers and over seventy-five percent currently practice in primary care settings. Further, over 174,000 nurse practitioners, nearly eighty-five percent of the current NP workforce, are treating Medicare beneficiaries. NPs are the health care provider for many of the beneficiaries located in rural and underserved areas.

After reviewing the legislation we are encouraged by the provider neutral language of the draft bill. There are, however, a few provisions we would like to see changed in order to maintain the provider neutral integrity of this bill. These provisions include:

- Section 1022, Pg. 22, Line 1
- Section 1122, Pg. 84, Line 6
- Section 1123, Pg. 85, Line 11
- Section 2021, Pg. 145, Line 12, 13, 15
- Section 2081, Pg. 164, Line 2
- Section 2091, Pg. 189, Line 11
- Section 4283, Pg. 315, Line 4
- Section 4301, Pg. 321, Line 10, 16
- Section 5082, Pg. 371, Line 7

Ensuring that all appropriate health care providers, including nurse practitioners, are fully included in these provisions will help to reach the goal of increasing patient access to high quality health care while driving down overall healthcare costs.

In **Section 4181: ADVANCING TELEHEALTH OPPORTUNITIES IN MEDICARE**, we support your efforts to expand telehealth as a model of care delivery and recognize that technological advances can both reduce cost and increase patient access to care across the country. As you know, nurse practitioners have been providers of telemedicine services for many years. We would like to commend the Committee for the actions proposed in this section to further expand the telehealth program within Medicare which would allow all providers, including NPs to participate in the program.

We strongly support the provision located on page 297 under **(1) WAIVER OF CERTAIN MEDICARE TELEHEALTH LIMITATIONS FOR PURPOSES OF DEMONSTRATIONS AND MODELS.** This provision prohibits limitations "on what qualifies as an originating site, any geographic limitation, or any limitation on the type of health care provider who may furnish such services." AANP supports the Committee's decision to lift the current location based restrictions on telehealth as well as limitations on the type of provider rendering care. The inclusion of this provider neutral provision will help to ensure that patient access to care is not limited by obsolete statutory requirements.

The Association does, however, request that one provision be adjusted in this section on page 299 under **(c) SENSE OF CONGRESS REGARDING STATE MEDICAL BOARD COMPACTS.** AANP acknowledges the importance that health care compacts can have on the effectiveness of telehealth. It is important that this section acknowledge different health care practitioners and their respective state boards that are, or soon will be, utilizing this delivery model. Therefore, AANP requests that this section be broadened to include all professionals utilizing and developing interstate compacts in the course of their practice.

AANP's suggested language is as follows:

> "Sense of Congress Regarding State Health Licensing Board Compacts – It is the sense of Congress that States should collaborate, through the use of State health licensing board compacts, to create shared jurisdictional authority, share investigative and disciplinary information and implement a strategy that enables license portability for the purposes of facilitating telehealth across state lines by health care providers while simultaneously ensuring protection of the public."

Lastly, we ask that the wording located on page 291 line 1, **Subtitle I – Telemedicine** be changed to Telehealth so that there will be no confusion concerning the range of providers included in all parts of this legislation.

In closing, we look forward to working with the Committee on a final piece of legislation that will increase access to high quality care. AANP is eager to have this forward thinking legislation move through the legislative process and are happy to serve as a resource at any time.

Sincerely,

[redacted]

David Hebert
Chief Executive Officer

CC:
Ranking Member, Energy and Commerce Committee, Frank Pallone
Chairman, Energy and Commerce Health Subcommittee, Joseph Pitts
Congressman Gregg Harper
Congresswoman Doris Matsui
Congressman Bill Johnson
Congressman Peter Welch
Congressman Greg Walden
Congressman Robert Latta

AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

February 13, 2015

The Honorable Fred Upton, Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Ranking
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone,

On behalf of the American Association of Orthopaedic Surgeons (AAOS), which represents over 18,000 board-certified orthopaedic surgeons, I would like to express we applaud the House Energy and Commerce Committee for developing the 21st Century Cures, an innovative proposal that accelerates the pace of cures in the United States. This forward-looking framework has the potential to accelerate innovation, boost research, streamline drug and device approvals, and enhance telemedicine, all of which will improve patient care exponentially.

Overall, the AAOS is very supportive of the proposal, though we do have a few reservations. Our positions on specific provisions are outlined below.

Title I

Subtitle A, Section 1001: We believe that establishing a framework for the incorporation of patient experience data into the regulatory decision-making process could provide a foundation for expanding this practice to devices, which would be beneficial to patients.

Subtitle F, Sections 1081-1082: In addition to accelerating the approval process, equal emphasis should be placed on streamlining the physician interface with the agency to facilitate access to devices for patients with limited therapeutic options. Any acceleration should not occur at the expense of safety and effectiveness, but should clearly define how the performance of the device will be tracked and what parameters will be used to determine appropriate levels of risk.

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Subtitle K, Sections 1201-1202: We strongly encourage a focus on funding translational research.

Subtitle K, Section 2081: We applaud the effort to work toward the goal of a national interoperable health information infrastructure.

Subtitle K, Section 2085: We strongly support the proposal to require the Health and Human Services (HHS) Secretary to make Medicare, Medicaid and CHIP claims data available to medical specialty societies and Qualified Clinical Data Registries (QCDR). We are concerned, however, that the proposal requires the HHS Secretary to charge a fee to QCDR's to cover the cost of such data. AAOS strongly urges the Committee to remove the fee requirement on QCDR's and qualified registries or to give the HHS Secretary the discretion to reduce or waive the fee if the data is being used to support public purposes and policies as well as the quality programs implemented by CMS.

Subtitle K, Section 2087: AAOS strongly supports the inclusion of language requiring the HHS Secretary to establish an exception to the Common Rule that allows clinical data registries to comply with the privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPPA) instead of comparable provisions of the Common Rule. AAOS would suggest that the final legislation be specific and give the Secretary discretion on the nature and the scope of this exception. We recommend that, at a minimum, the exception apply in situations where individuals or entities are only collecting identifiable patient information, but are not engaged in direct human subject intervention or interactions such as clinical trials and are following all HIPPA requirements with respect to protecting the privacy and security of such information.

Subtitle K, Section 2092: The AAOS supports several of these recommendations, including the promotion of bidirectional exchange of information between electronic health records of reporting physicians and registries. The lack of interoperability between electronic health records (EHRs) and clinical data registries has been a serious impediment to this data collection effort. AAOS encourages the Secretary to adopt and issue interoperability standards, implementation specifications, and/or certification criteria to ensure meaningful and timely exchange of information between certified EHFs and QCDRs. Meeting these interoperability standards should be a condition of certification for EHF technology for Meaningful Use purposes.

Title II

Subtitle B, Section 2012: The creation of a Medical Product Innovation Advisory Commission is unnecessary and creates additional layers of bureaucracy that may inhibit, rather than stimulate, innovation. All of the activities described herein are duplication of efforts that are currently being performed through various agency, industry, research, and clinician interactions.

Subtitle C, Section 2041: As many of these technologies are being used in young patients, including women of childbearing age, it is critical that long-term effects also be defined so that patients and surgeons may engage in well-informed shared decision making about the benefits and risks of these therapies.

Subtitle I, Section 2141 & 2142: Combination productions including biologics and/or tissue should be included in this initiative. This is a rapidly expanding area in orthopaedics and clear guidance is needed to facilitate applications for novel technologies.

Title II

Subtitle A, Section 3002: The acceptance of a universal International Review Board (IRB) review by local institutions and other amendments to the current implementation of IRB practices are critical to increasing patient access to novel therapies.

Subtitle E: Easing of restrictions on travel for the Food and Drug Administration (FDA) personnel would enable relevant staff to participate in educational and technical meetings that would augment their understanding of the current use of various technologies, which would inform the kind of testing and evaluations that would be most valuable in assessing the safety and effectiveness of new products. Increased interactions between FDA personnel, researchers, clinicians, and other stakeholders would facilitate the timely flow of information and support innovation.

Title IV

Subtitle H, Section 4161: The AAOS supports reforming the Medicare local coverage determination process.

Subtitle I, Section 4181: We support the provisions in the proposal that would advance opportunities for telemedicine and new technologies to improve the delivery of quality health care services to Medicare beneficiaries.

Subtitle K, Section 4221: The provision would allow seniors to better identify the out-of-pocket costs they might face for a given treatment or service and pick the service that is right for them and their budget. AAOS supports it.

Subtitle L, Section 4241: AAOS strongly supports nullifying the final rule published on November 13, 2014 relating to transitioning and revaluing 10-day and 90-day global services with 0-day global periods.

Subtitle M, Section 4261: We support requiring CMS to analyze and seek public input on how proposed Medicare payment policies would affect the consolidation of providers and payers.

Subtitle N, Sections 4281-4284: These provisions could be problematic for some patients. Limiting enrollees suspected of abuse to one or two pharmacies may be burdensome, especially in rural areas with long travel times. We like the fact that the provisions include an appeal mechanism. It may also be unreasonable to require that Schedule II, III, IV, and V controlled substances only be prescribed electronically. This may not be reasonable in rural areas or inner cities.

Subtitle S, Section 4381: The AAOS is supportive of clarifying that peer-reviewed journals, journal reprints, journal supplements and medical textbooks are excluded from the reporting requirement under the Sunshine Act.

Title V

Subtitle A, Section 5001: Extension of exclusivity for biosimilars may not be in the best interest of orthopaedic patients. Biosimilars differ significantly from generic drugs and are not necessarily interchangeable with the original product. For this reason, limiting patient's access to alternative biosimilars for any period of time, let alone an extended period, may force some patients to use name brand biologics, at a higher cost, or expose them to less effective therapies.

Subtitle D, Sections 5061-5068: The changes to the Humanitarian Device Exemption (HDE) provision are for IVDs, which are not solely used in orthopaedics. We strongly support the change to the Humanitarian Use Device exception, provided it is not abused by those seeking to circumvent other pathways.

Subtitle E, Sections 5081-5088: A secure supply chain is an important tool in providing surgeons and patients with reasonable assurance that they are using/receiving the device they intend. We have heard reports, through the Orthopaedic Device Forum, of thefts from warehouses and the challenge in tracking those products to prevent sale and use outside authorized channels.

Thank you for your consideration. If you have any questions or would like additional information, please contact Julie Williams at the AAOS Office of Government Relations at jwilliams@aaos.org or 202-546-4430.

Sincerely,

Frederick M. Azar, MD
President

American Brain Coalition

February 10, 2015

The Honorable Fred Upton
Chairman
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The Honorable Diana DeGette
Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Sent via e-mail: cures@mail.house.gov

Re: Regarding the 21st Century Cures Act discussion draft

Dear Chairman Upton and Representative DeGette:

The American Brain Coalition (ABC) applauds the Energy and Commerce Committee for its continued commitment to the 21st Century Cures Initiative. We congratulate the many Representatives who have contributed to this overarching discussion draft of the 21st Century Cures Act and appreciate the opportunity to comment on this proposed legislation on behalf of our organizational members, who represent nearly one sixth of the population of the United States.

The ABC is a non-profit organization comprising many of the United States' leading patient advocacy and voluntary health organizations, as well as professional neurological, psychological, and psychiatric associations. We enjoy the support of a small number of publicly-traded corporations that actively engage in brain-related research. Together, we seek to advance the understanding of brain functions and reduce the burden of brain disorders through public advocacy with the Congress, the administration, and the general public.

The ABC provides a strong and powerful voice for the 50 million people with disabling brain disorders, bringing together organizations that represent concerned and interested patients, families, and professionals. We advocate for:

1. Increased support of research that will lead to better treatment,
2. Services and support that will improve patients' quality of life, and,
3. A national commitment toward finding cures for individuals with disabling neurological and psychiatric disorders.

We continue to share your initiative's stated goal - to accelerate "the cycle of discovery, development, and delivery of promising new treatments and cures." This goal clearly addresses the continuum of activity from basic to translational to clinical research through the regulatory processes of approval and ultimately to payment by public and private payers. The 21st Century Cures Act draft adjusts key activities of the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Center for Medicare and Medicaid Services (CMS). From the perspective of patients, providers and researchers, each of these elements must work in concert to maximize overall benefits. Great discoveries in the lab do no good if they are never tested at the bedside. Successful treatments that meet high quality standards are useless if they are not covered by insurance companies for and accessible to patients.

The study of brain-related disorders is faced with many puzzles about normal brain mechanisms and brain dysfunction. There are regulatory problems – aspects of dealing with "safety and efficacy" standards that are difficult yet absolutely essential for brain research. These include legislative issues related to patent law and exclusivity standards. In addition, there are reimbursement and payment issues, where needs to control costs collide head-on with the obligation to address and relieve genuine human suffering. We previously proposed several countermeasures to overcome barriers to developing and delivering innovative treatments and cures to patients with neurological disease. Below please find our initial thoughts on how the discussion draft of the 21st Century Cures Act delivers on the priority areas we outlined in our October 15, 2014 statement to the Energy and Commerce Committee.

Harmonizing Activities Related to Discovery, Development, and Delivery

We support the creation of the 21st Century Cures Consortium (TITLE II: SUBTITLE A) aimed at fostering collaborations and establishing an agenda for accelerating the discovery, development, and delivery of innovative cures, treatments, and preventive measures for patients. Representatives from the patient and research communities, healthcare providers, and industry must have a voice as the Consortium develops recommendations on how to fill gaps and realize opportunities in the discovery, development, and delivery cycle. We are pleased that the Consortium will solicit feedback from stakeholders through their participation as Consortium members, officers, employees, agents, contractors, and Consortium committee members. We recommend that Congress also require that the Consortium gather stakeholder feedback through a public commenting process with appropriate Federal Register notice and opportunity to submit written testimony. To further ensure that any thoughtful idea generated has the best opportunity to be translated into action, we urge Congress to instruct the Consortium to provide legislative recommendations in its reports to relevant Congressional committees.

Sustainable R&D Funding

We understand that funding is under the jurisdiction of the Appropriations Committee. With all due respect, we strongly urge that the leaders of this effort reconsider their decision not to include overall funding increases to R&D activities in the 21st Century Cures Act. NIH funding levels must be set at a sustainable level of at least three percent above the rate of increase in the Biomedical Research and Development Price Index (BRDPI) to ensure that the United States remains competitive globally. There are numerous bills such as the American Cures Act introduced by Senator Richard Durbin and the Accelerating Biomedical Research Act sponsored by Representatives Rosa DeLauro, Brian Higgins, and Peter King that could serves a framework to grow our investment in the biomedical research enterprise in a predictable and sustainable way. Our need for improvements in health – and our international competitiveness – require nothing less.

The ABC endorses the financial support of several vital supplementary programs in the 21st Century Cures Act draft (TITLE I: SUBTITLE K which could provide additional funding to the Cures Acceleration Network at the National Center for Advancing Translational Science (NCATS); TITLE IV: SUBTITLE A, Section 4007 which could provide additional funding to the NIH Common Fund). We strongly support the Committee's inclusion of additional funding for Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative (TITLE IV: SUBTITLE A Section 4008). This program is already providing researchers with innovative tools to identify new ways to treat, prevent and even cure brain disorders. We urge the Committee to insert values that reflect strong support for all of these important programs.

The ABC also supports removing NCATS' phase IIB clinical trial funding restriction so that its activities align better with the activities of other institutes and centers at NIH.

R&D Funding Allocation without Political Interference

The ABC is very concerned with the inclusion of several provisions, listed below, that infringe upon the scientifically-driven peer review system that rigorously evaluates and prioritizes proposals across the basic and clinical research spectrum and awards support to the most meritorious.

- TITLE II: SUBTITLE O – Helping Young Emerging Scientists
- TITLE IV: SUBTITLE A, Section 4001 – NIH Research Strategic Investment Plan
- TITLE IV: SUBTITLE A, Section 4004 – Increasing Accountability at the National Institutes of Health
- TITLE IV: SUBTITLE A, Section 4005 – GAO Report on Common Fund

These provisions over emphasize factors other than funding the most scientifically sound and impactful research. Specifically, we ardently oppose evaluating research by considering whether the work maximizes the return of investment. The value of investing in research and development comes from the accumulation of information gleaned from many studies over time, and it is often difficult or impossible to accurately predict which single project may lead to the next breakthrough. The NIH system for selecting which research proposals are funded is based on the likelihood for a project to exert a sustained, powerful influence on the research fields involved because the research proposal, in part, addresses a contemporary challenge in the field. We implore upon the Committee to remove the four provisions listed above. However, as set out below, we do support changes to the research enterprise that would further patient-centered research.

Alternative Models for Requesting and Funding Research Proposals

We urge the Committee to include a provision that mandates that NIH consider alternative models for requesting and funding proposals that target the translation of basic research to therapeutic development. TITLE IV: SUBTITLE A, Section 4002 would establish the Biomedical Research Working Group composed of NIH and stakeholders to provide recommendations on how to streamline the grant process for researchers. It further instructs the NIH Director to implement measures to reduce administrative burden and enhance replicability of NIH-funded research. This provision partially addresses our earlier recommendation to create a model that enables a substantially more rapid review of proposals, prompt funding decisions, and sharing of research findings as rapidly and efficiently as possible. However, the ABC believes that the Biomedical Research Working Group should consider a more complete approach to streamlining the granting process.

Focus Areas for the Research Enterprise

Several specific research areas require greater focus and effort from the federal research enterprise. These include:

- The need to strengthen the connections between basic neuroscientists and translational researchers working on the development of diagnostics and therapeutics;
- Addressing the enormous issue of providing the infrastructure for, management, analysis, interpretation, as well of the associated costs of the huge datasets that now routinely confront biomedical research,
- Determining the most efficacious methods for training researchers given the fast-paced changes in the field so as to improve reproducibility generally and enable them to create data that is easily shared and useful for translational research where appropriate, and
- Enabling researchers working on related projects to collaborate and coordinate.

The provision Federal Data Sharing (TITLE II: SUBTITLE L) takes an important step toward encouraging collaboration and data sharing in biomedical research. ABC strongly supports the focus of this provision on protecting patient privacy, but recommends that the exceptions to data sharing based on trade secret or other protection be carefully reviewed to ensure that the exceptions do not limit the primary purpose of the provision. In addition, the ABC recommends that the 21st Century Cures Act mandate that a committee or committees within the 21st Century Cures Consortium (TITLE II: SUBTITLE A) address the four focus areas listed above in this section.

Incentivizing Investment in Drug Development

Congress provides incentives to private companies, venture capitalists, and philanthropies to take on the most difficult research tasks – such as mental illness and neurodegenerative disease medication and device development. The current incentive framework rewards companies for researching and developing treatments where development is relatively easy and products can be brought to market sooner. ABC believes that the incentive provisions included in the 21st Century Cures Act draft are important first steps forward to encouraging the development of drugs for complex diseases and disorders, and not necessarily products that are easy to develop and manufacture.

The ABC is pleased that the Dormant Therapies section (TITLE I: SUBTITLE L) would reward investment in treatments and cures for patients where there are unmet medical needs. A crucial aspect of this provision is that the dormant therapy protection period would begin once a new product is approved by the FDA. The timeline for developing therapies for complex neurological diseases and disorders is often lengthy and cuts into protection period afforded by traditional patents. Having a predictable period through which a company can recoup its investment would incentivize the development of future

medical products for unmet needs. On the other hand, generic drugs have a significant impact on reducing costs for patients and payers. Any incentive framework should balance the various interests of the patient. The ABC recommends that the Committee re-evaluate and consider shortening the protection period in this provision unless it can be shown that the proposed 15-year period is necessary for this type of an incentive to be effective in redirecting industry R&D efforts. Finally, the assertion that this provision would eliminate the potential for delaying generic drug entry though patent settlement agreements should also be validated.

We support two other provisions in the draft that incentivize repurposing already approved drugs (TITLE I: SUBTITLE M—New Therapeutic Entities) and exploring new uses for drugs for rare diseases (TITLE I: SUBTITLE N—Orphan Product Extensions Now).

FDA Funding & Training

FDA must be assured sustainable and robust funding – from user fees paid by industry and from government support – to prevent bureaucratic delays in the processing of applications for new drugs, biologics and devices, while assuring safety and efficacy are maintained at the levels American patients have come to expect. Every effort must be made at the FDA to recruit the "best and the brightest" of scientific minds and to retain them at the agency. It is also important to provide appropriate professional opportunities and incentives that promote excellent work from FDA staff. Continuing education programs, attendance at scientific conferences, and merit-based bonus payments are all key factors in promoting efficient, high level work at the agency which facilitates more rapid and thorough FDA review.

The ABC endorses TITLE IV: SUBTITLE F—FDA Succession Planning in the 21st Century Cures Act which would provide opportunities for professional development and training for FDA staff in topic areas relevant to their field. The ABC is also pleased to see that FDA would be instructed to create a formal succession plan to recruit talent from within the Agency to management positions. Additionally, the ABC looks forward to reviewing the language for TITLE IV: SUBTITLE E—FDA Hiring, Travel, and Training. We recommend that it specifically enhances FDA's ability to recruit talent from outside the Agency and that it contain no restrictions (other than those occurring as a result of sound management practices) on travel to scientific conferences. These meetings represent a significant source of updating FDA (and other) employees' knowledge base.

Promoting Patient and Caretaker Engagement

The ABC thanks the Committee for including the provision Patient Focused Drug Development (PFDD; TITLE I: SUBTITLE A) in the 21st Century Cures Act draft. ABC believes it is crucial to include the patient perspective in areas such as risks and benefits, targeted endpoints, and meaningful outcomes, and thus fully supports the enhancement of the PFDD program. The community will need to have clarity on how the risk-benefit assessment framework in the new drug approval process will affect regulatory decision- making. The ABC looks forward to working with the FDA through the public comment period and at the public workshop on this important topic.

Expedited Payment Systems for (Central Nervous System) CNS Products

The ABC believes that it is imperative that Congress empower CMS to create an expedited payment system specifically for breakthrough CNS-related products and treatments. We urge the Committee to include a provision that creates a system designed to assure prompt and fair payment to avoid unnecessary delays. Ensuring an objective and responsive decision-making process for CMS payment systems will further incentivize investment and assure that the best products are readily available to the largest number of consumers. It is clear that the Committee is considering language on CMS coverage for breakthrough devices (TITLE I: SUBTITLE E). We encourage the Committee to include a provision that would allow for an expedited payment system for breakthrough CNS medical drugs and biologics.

Innovation Tax Credit

While not within the Committee's jurisdiction, tax laws must be adjusted to eliminate unintended penalties that dissuade investment, which could be accomplished by providing appropriate credits for innovative research and development investments. Specific consideration should be given to creating an Innovation Tax Credit, similar to what is done in Canada

and the UK, whereby companies may write off the costs of development of new products that significantly advance the field. Targeting the tax credit to areas of high need, such as CNS products, would make it more valuable and efficient in achieving results. These tax credits would not cost anything upfront and would encourage companies to invest in complex and difficult research areas.

NIH Travel Policy

Scientists at NIH conduct some of the most innovative and high-priority research addressing the most difficult biomedical challenges that our nation faces. The research that they do not conduct, they fund. NIH researchers must be able to exchange emerging scientific findings, discuss new theories with other thought-leaders in their fields, and explore new technological approaches at premiere conferences both locally and abroad. At these venues, NIH researchers have access to data frequently shared in advance of its release in journal publications. Often many thousands of scientists in a particular field travel to engage in these scientific exchanges. We note that the Committee has left a placeholder for language relevant to amending NIH travel policy. To ensure that NIH researchers and program managers continue to have full access to the latest scientific information, the ABC advocates for greatly tempering the overly restrictive NIH travel policy. Thus, the ABC recommends that a provision on NIH travel policy rescind restrictions (other than those occurring as a result of sound management practices) on travel to scientific conferences.

National Neurological Disease Surveillance System

Neuroscientists are making great strides in many areas of brain research, but they need more information. As stated before, neurological diseases affect up to 50 million people in the United States. However, we lack essential information to assist those who research, treat, and provide care to those suffering from these diseases in our communities. The Advancing Research for Neurological Diseases provision (TITLE IV: SUBTITLE B) would provide accurate data to researchers on incidence and prevalence, as well as risk factors, how diagnosis and treatment varies by gender, ethnicity, and region, and importantly, how these trends change over time. We thank the Committee for including it in the 21st Century Cures Act draft and fully endorse its inclusive in the final version.

Conclusion

The American Brain Coalition and its 85 nonprofit and for-profit members, individually and collectively, represent a significant portion of the stakeholder community in the field of neuroscience. Many of them have, and will, issued their own specific recommendations to the Committee. Collectively as an organization and on behalf of our members individually, we thank you for the enormous effort you have invested in drafting this important piece of legislation and for further considering our positions. The ABC is eager to continue working with the House Energy and Commerce Committee, as well as with the entire Congress, to pass the best version of this bill so that we can accelerate access to new treatments and cures.

If you have any questions or require any further information, please contact Katie Sale, ABC's Executive Director at ksale@americanbraincoalition.org or 763-557-2913.

Sincerely,

Robin Elliott
Chair
American Brain Coalition

AGS | THE AMERICAN GERIATRICS SOCIETY
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February 20, 2015

The Honorable Fred Upton
Chairman
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Committee on Energy and Commerce
2368 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette,

The American Geriatrics Society (AGS) greatly appreciates the opportunity to comment on several important aspects of the 21st Century Cures Discussion Draft. The AGS is a not-for-profit organization comprised of more than 6,000 health professionals who are devoted to improving the health, independence and quality of life of all older people. Our vision for the future is that every older American will receive high quality patient-centered care. Research is a key avenue for achieving this vision. We greatly appreciate your interest in and support for health research that will promote medical innovation and impact the way we treat disease. This is an important opportunity to think about ways in which we can improve on and address the health care needs of aging Americans. Below we have made some recommendations on select provisions that we hope you consider as you work to further develop this discussion draft.

TITLE II - BUILDING THE FOUNDATION FOR 21ST CENTURY MEDICINE INCLUDING HELPING YOUNG SCIENTISTS

Subtitle F - Building a 21st Century Data Sharing Framework

Section 2092 of Subtitle F requires the Secretary of Health and Human Services make recommendations for the development and use of clinical data registries, including recommendations for a set of standards that "would allow for the bidirectional, interoperable exchange of information between the electronic health records of reporting clinicians and such registries." AGS supports the sharing of data and recognizes the vast potential for electronic health records (EHRs) to improve the quality and coordination of care for geriatric patients.

However, we are concerned that single disease registries may not meet the needs of patients living with multiple chronic conditions (MCC). Chronic conditions are common among older adults, and many older adults have more than one chronic condition. Single disease registries should include data adequate to distinguish patients with multiple chronic conditions. A patient with congestive heart failure and hypertension in mid-life has very different healthcare needs and outcomes than a patient with congestive heart failure, chronic lung disease, moderate dementia and diabetes.

Additionally, efforts to promote the interoperable exchange of information should take into account that Medicare beneficiaries are often cared for in multiple care settings, including the office, hospital, post-acute and long-term care facilities. Integrating their care and treatment across settings is an important goal and one that needs to be addressed.

Subtitle G - Utilizing Real-World Evidence

AGS is concerned about the FDA program established in Section 2101 of Subtitle G that would use "real-world evidence," including data from registries, to support regulatory decision-making because currently there is no consensus on the best methods for collecting such evidence for this purpose. We believe that due to the limitations of registry data in particular, this section would need to include an effort to further specify how the data would be used, including but not limited to, identifying potential rare harms and informing funding for subsequent trials with appropriate methodologies to reduce bias. Given the need to further understand how to utilize these data, we strongly suggest that the FDA create a program that will research the best method for collection rather than issuing public guidance.

Subtitle O - Helping Young Emerging Scientists

AGS members include medical researchers specializing in the field of aging. These researchers are working on pioneering projects on issues such as the effects of sleep medication on hip fractures and postoperative delirium in the elderly, to name a few. We have heard, first-hand, about the particular difficulty of new investigators to remain in medical research because of a lack of, or uncertainty regarding sustained funding. We recognize the importance of increasing National Institutes of Health (NIH) support for investigators with innovative and creative ideas in the early stages of their career.

AGS recently sent a survey to investigators, which can be accessed here, to better understand the impact of federal budget cuts to aging-related research on investigators, institutions and medical progress. We found that investigators are overwhelmingly "very worried" or "moderately worried" that federal funding limitations will prevent them from maintaining their lab or research agenda over the next ten years. Of note, over 57 percent of respondents said that compared to five years ago the pipeline of new investigators planning a career in aging research has decreased in their research program or center.

We wholeheartedly support efforts to enhance the academic and career development of new investigators, and appreciate Congressman Andy Harris' leadership on this issue. We are, however,, concerned about the funding mechanism.

Specifically, the proposal in Sections 2261-2262 to redirect funds from the Public Health Service Evaluation Set-Aside, known as the "evaluation tap," that totals about $700 million per year, back to the NIH to support grants for emerging scientists would come at the expense of many important programs critical to assessing and improving health.

We urge the Committee explore other sources of funding for this important initiative, which will make an important difference in recruiting and retaining researchers with deep expertise in aging matters.

Subtitle N - 21st Century Chronic Disease Initiative Act

AGS shares the concerns expressed by the Friends of the National Institute on Aging (FoNIA) regarding the 21st Century Chronic Disease Initiative Act, which would implement a plan to carry out a longitudinal study designed to improve the outcomes of patients with chronic disease. As stated by the coalition, "a new study would be redundant to existing similar projects, would risk diverting scarce resources (capital, researchers and study participants) from other chronic disease research. For Alzheimer's disease in particular, we believe that the established national goal of preventing and effectively treating Alzheimer's by 2025 serves us well.

Title III - Modernizing Clinical Trials

Subtitle A - Clinical Research Modernization Act

Sections 3001-3002 would help streamline the institutional review board (IRB) process, particularly for clinical trials conducted at multiple sites, by minimizing regulatory duplication and unnecessary delays. AGS is supportive of efforts to streamline this process and supported in December 2014, the NIH draft policy that would require the use of a single IRB for multi-site clinical trials conducted or supported by NIH. We understand that IRBs are an important component of the clinical trial process. We believe that a modernized process as outlined in the NIH proposed policy will reduce inefficiencies so that research can move forward efficiently and avoid costly delays in study approval and start up while following all ethical principles and guidelines. Any additional plans to streamline data reporting and clinical trials should truly streamline the process and not simply create new procedures, as the existing framework is already overly burdensome for researchers.

General Comments - Clinical Trials

While not directly addressed in the discussion draft, AGS strongly urges you to consider the addition of language under this section to help guide the development of new policies to foster the participation of diverse patient populations in clinical trials. Older adults with poor health, disability and multiple morbidities are frequently excluded from randomized clinical trials; however, these are the individuals who generate a large share of health care costs, for whom there is little guidance on comparative effectiveness, and are most vulnerable to the adverse effects of medication.

Despite several decades of calls to action, the gaps in the evidence base for guidelines have never been larger. Among 22 Late-Breaking Clinical Trials presented at the 2011 American Heart Association Scientific Session, 8 trials did not include a single patient older than 65 years of age.[1] More than 50 percent of all trials for coronary artery disease in the past decade did not enroll a single patient ≥75 years of age. The geriatric population represented just 9 percent of all patients enrolled in such trials.[2] In October 2012 the American Diabetes Association published a "Consensus Statement on Diabetes in Older Adults" and concluded that "despite having the highest prevalence of diabetes of any age group, older persons…have often been excluded from randomized controlled trials…of diabetes."[3]

AGS has made several recommendations; most recently in a letter[4] to the Food and Drug Administration (FDA) request for comment on the issues and challenges associated with the collection, analysis, and availability of demographic subgroup data for FDA approved products. Our feedback outlines ways in which the FDA could increase awareness, improve processes, and eliminate barriers to enrollment. A link to our letter can be found in the footnote below. We would welcome the opportunity to speak with you about this issue in further detail.

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1 Green P, et al. Representation of Older Adults in the Late-Breaking Clinical Trials American Heart Association 2011 Scientific Sessions. JACC 2012; 60; 869-870.

2 Lee PY, Alexander KP, Hammill BG, Pasquali SK, Peterson ED. Representation of elderly persons and women in published randomized trial of acute coronary syndromes. JAMA. 2001; 286: 708–713

3 Kirman S, et al. Diabetes in Older Adults: A Consensus Report. J Am Geriatr Soc 2012.

4. American Geriatrics Society Comments to FDA. Docket No. FDA-2013-N-0745, Action Plan for the Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Human Medical Products, Public Hearing. May 2014.
http://www.americangeriatrics.org/files/documents/Adv_Resources/Comment.Letter05.15.14.pdf

TITLE IV - ACCELERATING THE DISCOVERY, DEVELOPMENT, AND DELIVERY CYCLE AND CONTINUING 21ST CENTURY INNOVATION AT NIH, FDA, CDC, AND CMS

Subtitle A - National Institute of Health

AGS strongly supports Section 4007 to authorize additional funding for the NIH Common Fund. The NIH Common Fund supports high impact cross-cutting research across multiple Institutes. The National Institute on Aging (NIA) is involved in several of these efforts, which are designed to overcome major research barriers. The Healthy Brain Project is one of the many important initiatives that have been funded through the NIH Common Fund. The ultimate goal of this effort is to ascertain effective and practical measures that can be utilized by the public and healthcare providers to promote cognitive and emotional health in older adults. This is a joint initiative of the NIA, the National Institute of Mental Health (NIMH) and the National Institute of Neurological Disorders and Stroke (NINDS).

AGS also supports additional funding for NIH Brain Research and specifically the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative. This is an important initiative aimed at revolutionizing our understanding of the human brain. This groundbreaking program could help researchers find and create effective ways to care and treat those suffering from various neurological and psychiatric disorders, including Alzheimer's, depression and Parkinson's Disease, to name a few.

More resources will allow the NIH to continue to prioritize aging research across institutes. The Institutes that make up the NIH, and in particular the NIA, lead the national scientific effort to understand the nature of aging and to extend the healthy, active years of life. Robust medical research in aging is critical to the development of medical advances which will ultimately lead to higher quality and more efficient healthcare. Continued federal investments in scientific research, including comparative effectiveness initiatives, will ensure that the NIH has the resources to succeed in its mission to establish research networks, assess clinical interventions and disseminate credible research findings to patients, providers and payers of health care. One example of research specific to older adults is the PCORI-NIA comparative effectiveness project, *Strategies to Increase confidence, InDependence and Energy (STRIDE)* that is looking at falls in older adults. We believe that increased investment in projects that focus specifically on older adults will lead to improved health and, perhaps more importantly, quality of life for this population.

Subtitle I - Telemedicine

AGS supports policies and regulations that bring the expertise of geriatrics to patients and families, and therefore agrees with the proposal outlined in Section 4181 of Subtitle I to expand the number of teleheath services covered by Medicare and limit geographic restrictions. Telehealth services play an important role for home-bound older adults and those living in rural and underserved communities. About 62 million Americans rely on rural health providers, and rural areas of the U.S. have fewer than half as many primary care physicians per 100,000 people as urban areas of the U.S. Rural patients often have to travel long distances to reach a physician, which can be especially challenging for older adults who often have more medical appointments and difficulty traveling compared to younger persons.

Subtitle N - Medicare Part D Patient Safety and Drug Abuse Prevention

Sections 4281-4284 under Subtitle N outlines a proposal aimed at preventing high-risk Medicare beneficiaries from abusing controlled substances. AGS shares your concern about the misuse of scheduled medications; however, any proposal to address potential abuse will need protections in place to ensure that beneficiaries who need these medications for legitimate reasons have access to them. Specialists with knowledge in treating conditions that require the use of frequently abused medications

should play a key role in developing the criteria that will be used to identify at-risk beneficiaries. This and other important recommendations, including how to handle multiple prescribers, have been outlined in detail in a November 2014 issue brief[5] developed by the Leadership Council of Aging Organizations (LCAO), of which AGS is a member. The brief highlights several important beneficiary protections that we support and believe you should consider.

A further concern that AGS has includes situations where a beneficiary may live in a rural area where the designated pharmacy is not conveniently located to patients. There should be protections in place to ensure access for these beneficiaries who may only have access to one pharmacy due to their geographic location and travel time.

Another concern is the issue around multiple prescribers. Multiple prescribers would need to be defined to allow for prescribers from the same practice cross-covering one another as well as teaching facilities where providers rotate. The other issue is the use of multiple pharmacies. If the "locked in" medications are filled in one pharmacy and all the other medications are filled in the patient's usual pharmacy, there is the potential to miss drug interactions. Further, the patient's doctor may resort to prescribing other - and maybe less effective or appropriate - medications that do not fall into the "locked in" list.

Again, we appreciate the need to address the misuse of scheduled medications but urge you to develop the program in a way that will ensure no harm to the Medicare beneficiaries that need these medications.

TITLE V - MODERNIZING MEDICAL PRODUCT REGULATION

Subtitle D - Medical Device Reforms

Section 5068 under Subtitle D creates processes to ensure that an advisory committee selected to review a medical device submission has adequate expertise to assess "the diseases or condition for which the device is intended to cure, treat, mitigate, prevent, or diagnose." AGS believes that any effort to strengthen and improve the advisory committees should require the FDA to safeguard the unique health care needs of older adults by establishing a Geriatrics Advisory Committee.

While older adults represent a significant percentage of the population treated, the FDA continues to approve devices and therapeutics with little, if any, data in this population. We envision that a newly formed Geriatrics Advisory Committee would act in a manner similar to the already-established Pediatric Advisory Committee to the FDA. This group would serve a valuable role to (1) advise and make recommendations to the Commissioner of Food and Drugs regarding geriatrics research; (2) identify research priorities related to the need for additional treatments for specific conditions of aging; (3) review the ethics, design, and analysis of clinical trials related to therapeutics to be used in older adults; (4) help mediate geriatric labeling disputes; (5) assist in mediating geriatric labeling changes; (6) survey adverse event reports for drugs used in older adults; and (7) serve in any other matter involving older adults for which FDA has regulatory responsibility.

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[5] Leadership Council of Aging Organizations. *Medicare Part D "Lock-In" Proposals Must Include Beneficiary Protections.* November 2014. http://www.lcao.org/files/2014/11/FINAL-LCAO-LockIn-Part-D-Brief.pdf

We thank you for this opportunity to comment. Should you have any questions or would like to discuss anything in greater detail; we welcome the opportunity to speak with you. Please contact, Alanna Goldstein at agoldstein@americangeriatrics.org or 212-308-1414.

Sincerely,

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February 23, 2015

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Committee on Energy & Commerce
U.S. House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate your leadership and comprehensive approach to identifying legislative proposals that would accelerate the discovery, development, and delivery of new cures. The AMA welcomes the opportunity to comment on this initial draft of the "21st Century Cures Act" (Cures). Physicians, along with patients, are at the forefront of a fundamental transformation in healthcare resulting from the intersection of genetic and genomic breakthroughs, the rapid growth of digital capabilities, and the resultant new tools for patients and physicians. Leveraging these new capabilities will require new pathways for research where patients and physicians have a greater role as part of a learning health care environment, strategic modernization of regulatory oversight, coverage and payment flexibilities, and, critical to all the foregoing, development of a workable, interoperable data sharing infrastructure. In our prior comments to the Committee, the AMA outlined needed reforms in five areas that directly impact physicians' ability to deliver high quality care to patients in this new environment: 1) electronic health records (EHRs) and 21st Century technology; 2) telemedicine; 3) personalized medicine and laboratory developed testing services and procedures; 4) antibiotic development; and 5) protecting patient data. We appreciate that the Committee included provisions in the draft legislation that address a number of areas we outlined and include comments below on those and other provisions.

As a threshold matter, the AMA appreciates that the Committee continues to deliberate in a number of key areas of significant interest to physicians and their patients. Specifically, there remain placeholders for interoperability, precision medicine, and modernizing regulation of diagnostics. We would welcome the opportunity to meet with the Committee to discuss in greater detail our recommendations in these critical areas.

Section 2181. Interoperability

The AMA looks forward to additional information on Section 2181 concerning interoperability and working toward the goal of an interoperable health information infrastructure. The promise of 21st Century cures is inextricably linked with the ability of physicians and patients to use technologies that support effective communication and that allow them to move information seamlessly through the health care continuum. However, there are substantial barriers to making the foregoing a reality.

It is not possible to divorce the lack of an interoperable health care infrastructure from the prescriptive nature of the Meaningful Use (MU) program. The MU statute requires physicians to use certified EHRs in order to meet MU requirements. While the statute lists a discrete set of MU requirements—one of which is interoperability—the implementation of this program has resulted in a substantial expansion of the program, adding numerous and overly complex measures that have nothing to do with data exchange. Vendors must prioritize their development process to meet this unwieldy set of mandates in order to obtain certification. What this means is certified systems are created with the MU requirements as the first priority while physician client needs (and thus patient needs) are a distant second. The MU requirements are in effect a barrier to interoperability because they are taking away valuable time and resources that could be better spent addressing the key issue of interoperability.

Prior to MU, the early development of EHRs was centered on customer needs and was poised to flourish in a traditional consumer-driven marketplace. Although well intended, the heavy handed approach of the MU program is marked by regulatory overreach which is stifling innovation and is negatively impacting the adoption of new technologies. The program is excessively burdensome to vendors, physicians, and medical staff alike. In particular, the challenges physicians are experiencing with EHRs that cannot interoperate is evidenced by their low participation in the MU program and the high level of dissatisfaction with these products. Many MU requirements are tied to the assumption that EHRs are fully capable of interoperability. This is not the case, and as a result, the majority of physicians may face MU penalties. To date, many have elected to take these financial penalties rather than continue investing in systems that lack interoperability and force them to care for patients in a manner that does not improve quality or drive efficiency.

We strongly urge the Committee to consider that improving interoperability and usability of EHRs is tied to streamlining MU regulations for physicians. Specifically, the AMA urges the Committee to consider more effective approaches to the MU program and regulation of health information technology including:

- Removing the Pass-Fail Approach of the Meaningful Use Program. The most immediate action Congress can take to improve interoperability and usability of EHRs is to address the rigidity of the 100 percent pass/fail rate for the MU program. Under the current program, physicians must meet 100 percent of MU requirements to earn an incentive and avoid a penalty. In turn, vendors must certify to meet all of the MU requirements. As discussed above, this prioritizes MU measures over interoperability and usability.

- Promote interoperability. The MU incentives were predicated on significant cost savings associated with exchanging information across EHRs. Data exchanged today, however, essentially amounts to multi-page documents that cannot be easily transmitted or incorporated into the patient's chart, reducing the utility of this information. Additionally, physicians are often charged tens of thousands of dollars for costly interfaces and data exchange fees. Importantly, the information stored and exchanged in the EHR is not in a usable format for quality improvement and lacks standardized data elements, data formats, and definitions. This is a cornerstone of interoperability that must be adopted to improve outcomes and eliminate administrative cost to clinicians, hospitals, and others who have to map their data differently every time they send it to an external entity.

- Streamline EHR certification. The Centers for Medicare & Medicaid Services (CMS) MU requirements and the focus of the Office of the National Coordinator for Health Information Technology (ONC) certification process should prioritize interoperability and EHR usability. The current process simply ensures that EHRs meets the MU measures without addressing if information can be exchanged, incorporated, and presented to a physician in a contextual and meaningful manner.

- Align various Medicare quality reporting programs. MU includes a separate quality reporting program. Better alignment of the Physician Quality Reporting System (PQRS) program and MU quality reporting requirements is needed. Physicians who meet the more robust PQRS quality requirements should be deemed as meeting MU. This will ensure that physicians are still reporting on quality measures to improve care and will reduce administrative burden by not having to report on quality measures twice.

- Expand current hardship exemptions. Expansion of hardships will provide more ways for certain categories of physicians who face specific obstacles to meet the MU program (e.g., physicians close to retirement where this practice investment does not make sense) can avoid penalties.

The foregoing are concrete solutions that will increase the capability of physicians and the health care system to adopt technology solutions that are the necessary prerequisite to changes in the current approaches to research, regulation, clinical practice, and insurance coverage. All of the foregoing enterprises require access to reliable, high quality data that is available along the continuum. Creating silos of information will not accelerate cures nor will it create the requisite efficiencies needed to leverage the benefits of next generation technologies.

Section 2161. Modernizing Regulation of Diagnostics

Physicians have been at the forefront of one of the greatest revolutions in medicine—the application of genetic knowledge to clinical practice. Physicians have been and continue to be at the intersection of providing patients' medical care and advancing clinical knowledge to improve upon the current standard of care. Millions of testing procedures are performed reliably, accurately, and safely every year running the gamut of simple clinical procedures to highly complex—including certain genetic and next generation testing services. It is estimated that approximately 70 percent of clinical decisions are guided in part by clinical testing. As a result, the AMA has serious concerns that the Food and Drug Administration's (FDA) proposal to regulate laboratory developed testing services and procedures will choke off the primary development pipeline for new diagnostics, deny patients access to treatments and cures, and compromise the nation's public health capabilities, including diminishing our ability to detect and combat bio-threats and infectious disease outbreaks.

The AMA is not alone in these concerns. During an FDA hosted two-day meeting in January on the Agency's proposed regulation of laboratory developed testing services, a wide array of stakeholders raised the same or similar concerns—including the association representing public health clinical laboratories and member laboratories. The latter in comments to the FDA's docket outlined a grim reality that the FDA's proposal would not only curtail the capacity and needed flexibilities of community laboratories that provide surge capacity during an outbreak, and sentinel network laboratories that provide detection capabilities for the public health laboratories, but every state's public health laboratory would be hamstrung should the guidance be finalized. Furthermore, the FDA's proposal will impose another

layer of regulation—beyond the Clinical Laboratory Improvement Amendments (CLIA) and, for many laboratories, third-party accreditors and state regulatory oversight. In addition, the FDA's proposal involves regulation of the practice of medicine—achieved by treating physician services and procedures as devices, a questionable legal fiction.

The AMA does agree that there is a need to modernize the existing regulatory framework for laboratory developed testing services that are offered by physicians to their patients and provided in laboratories subject to CLIA, as well as the regulations for commercial diagnostics kits mass produced by manufacturers that are currently regulated by the FDA. However, the steps for achieving the foregoing include modernizing CLIA by mandating third-party accreditation of all clinical laboratories and increased transparency of documentation of laboratory clinical and analytical validation. In addition, the AMA urges Congress to confer the FDA with explicit authority to regulate direct-to-consumer tests and testing services where incorrect results could cause harm to patients and the test methodology is not transparent nor well understood (as in the case of tests that use complex and proprietary algorithms to produce results). The AMA also supports streamlining the oversight for manufacturer commercial kits subject to FDA regulation, including greater flexibilities for manufacturers to incorporate modifications.

The push to regulate laboratory developed testing services appears to be related to concerns with highly complex genetic/genomic tests. The AMA agrees that a small subset of complex genetic/genomic tests, e.g., those that use proprietary and non-transparent algorithms that do not lend themselves to review and refinement by laboratory physicians and professionals, should be subject to oversight, potentially by the FDA. The AMA supports an oversight mechanism that would ensure the analytical and clinical validity of such tests. However, the FDA's proposed framework goes far beyond addressing those "black-box" tests, and instead subjects a massive number of laboratory developed testing services to costly and burdensome requirements that would add little or no value to the testing services but would severely disrupt their availability to patients and treating physicians. It is notable that this massive interruption in clinical practice and commitment of the FDA's time and resources into the development of a new infrastructure will divert limited time, resources, and effort from developing and implementing a viable and agile framework to address the complex regulatory challenges posed by next generation sequencing—a technology and method that will likely overtake existing methods the Agency is attempting to regulate. This will have implications for President Obama's Precision Medicine Initiative which will rely upon next generation sequencing along with whole genome sequencing to generate relevant breakthroughs.

Section 2301. Precision Medicine

The AMA is very interested in working with both Congress and the Obama Administration to advance a number of the broad objectives outlined to date concerning President Obama's Precision Medicine Initiative (Initiative) including the 1 million genome project that would be led by the National Institutes of Health (NIH). The Initiative is not limited to personalized medicine (genetic and genomic testing and related tailored prevention or treatments), but contemplates novel research methods, uses of digital health, and is premised on a level of data interoperability and databases that do not currently exist. The AMA looks forward to specific language related to Section 2301. It is notable that the final Cures legislation could have a significant impact on the feasibility of the Initiative. For instance, lack of interoperability will be a serious barrier to these efforts as already outlined during a two day NIH meeting concerning the million genome project. In addition, FDA regulation of digital health and laboratory developed testing

services will have implications for the million genome project's use of such tools to advance medical knowledge and patient engagement.

Section 4181. Telemedicine

The AMA strongly supports the Committee's efforts to remove restrictions on Medicare coverage of telemedicine services that do not reflect the magnitude of technological changes since the Medicare telehealth statutory provisions were adopted. The AMA urges the Committee to reimburse for more telemedicine services as well as to promote telemedicine that supports care delivery that is patient-centered, promotes care coordination, and facilitates team-based communication. We appreciate that the framework outlined by the Committee as part of Section 4181 attempts to expand coverage, but it may add extra complexity by establishing a second coverage pathway. We urge the Committee to consider a streamlined approach that the AMA supports by including:

- provisions of H.R. 4015/S. 2000, the "SGR Repeal and Medicare Provider Payment Modernization Act of 2014," that would allow telehealth services not currently covered under Medicare to be covered services for alternative payment models (APM) and qualifying APM participants, including Pioneer Accountable Care Organizations, to promote care coordination;

- expanded access to telemedicine services under the Medicare program by removing current geographic requirements under section 1834(m) of the Social Security Act; and

- coverage of telemedicine services for dual eligible beneficiaries to the same extent as their Medicaid-only counterparts.

Furthermore, the AMA supports additional Medicare pilot programs to enable coverage of telemedicine services, including, but not limited to, store-and-forward telemedicine. Because the coverage of and payment for telemedicine services are related to the evidence in support of telemedicine, the AMA encourages additional research to develop a stronger evidence base for telemedicine. The AMA continues to regularly meet with national medical specialty societies to provide support for their efforts to expand the evidence base—this will lead to clinical practice guidelines as well as information that insurers need when making coverage determinations. The AMA opposes federal legislation that would preempt or waive licensure and medical practice laws for telemedicine encounters and strongly affirms that physicians must be licensed in the state where the patient receives services. Therefore, the AMA appreciates the Sense of Congress language included in this section and has suggested relevant modifications to the Committee to reflect the nature and scope of the Federation of State Medical Board's Interstate Compact. **We welcome the opportunity to continue working with the Committee to identify flexibilities to increase telemedicine coverage in the Medicare program**.

Sections 1061-1064. Antibiotic Development

For years, AMA has recognized that antibiotic resistance represents a serious public health threat and strongly supports the inclusion of provisions in the draft legislation that would establish important incentives and pathways to accelerate development of next generation antibiotics. The AMA has publicly supported H.R. 3742**,** the "Antibiotic Development to Advance Patient Treatment Act of 2013" (ADAPT), and appreciates the inclusion of similar provisions in the draft legislation. While certain

prescribed activities outlined in these provisions may need to account for FDA capacity and resources, overall there is a compelling need for these provisions and **the AMA strongly supports the inclusion of these provisions in the legislation that is ultimately introduced.**

Section 2087. Quality Activities Clarification; and Sections 3001-3002. Clinical Research Modernization Act

The AMA strongly supports efforts to clarify and modernize the quality reporting infrastructure protections and those protections related to research involving human participants. To that end, the AMA strongly supports Sections 3001-3002 that would modernizes the requirements vis-a-vis institutional review board (IRB) processes, particularly for clinical trials conducted at multiple sites. These provisions will reduce regulatory duplication and unnecessary delays that have plagued research that spans multiple sites. This is essential to increase the number of research activities that seek scale—including, for example, the President's Precision Medicine Initiative Million Genome project. Furthermore, Section 2087 provides much needed clarification that quality improvement activities are not subject to the Common Rule. This has been a source of confusion and a resource drain for national medical specialties that, as part of quality improvement activities, have established clinical data registries and are already complying with the Health Information Portability and Accountability Act (HIPAA) privacy and security requirements. When institutions insist on compliance with the Common Rule requirements when the activities are for quality improvement, it has imposed substantial and costly barriers to these essential activities that improve patient health outcomes. **Therefore, the AMA strongly supports the inclusion of these provisions in the legislation that is ultimately introduced**.

Section 2091. Commission on Data Sharing for Research and Development; and Section 2092. Recommendations for Development of Clinical Data Registries

The AMA applauds the Committee's efforts to develop an infrastructure that can support the continuum of activities (research, regulatory, quality improvement, clinical decision support, and coverage, for example) that can be facilitated by state-of-the-art clinical data registries. National medical specialty societies have led the way in the establishment of such registries to support quality improvement, development of the evidence base, and other essential activities. However, we do have a few concerns related to sections 2091(b)(2) and 2092, which create new categories of registries/registry requirements that fail to take into account existing and developing quality registries (including Qualified Clinical Data Registries (QCDR)) for quality reporting under PQRS, Medicare value-based modifier, and MU. Specialties are devoting substantial resources to create and maintain registries. Quality registries are also being used for research purposes, post-market surveillance, coverage decisions, and reimbursement, not just for quality improvement. **We would like to work with the Committee and with medical specialties to ensure that the new language is harmonious with existing registry features and requirements**.

Ensuring interoperability is another critical challenge in this space. Taking initial steps to improve the underlying data captured within the EHR and registries is a key component of moving medicine forward, but one that requires a collective effort from the medical community. These definitions should be developed through a consensus process that includes all specialties and practitioners (not just physicians) who understand the clinical context of the data elements based on the patients for whom care is provided. Semantic interoperability, syntactic interoperability, and functional standards are key to establishing the data exchange consistency needed across health information technology. Any future benefits from

alternative payment models and value-based pay are premised on registries, vendors, and payers working with medical associations to establish this level of standardization. For physicians and the research community to fully realize the full potential of data aggregation the following things must occur:

- Interoperability between registries and EHRs. There are specific formats to move data and program language to exchange data. However, not all registries are operating on the same standards. There is a need to encourage registries, such as QCDR to exchange data with EHRs through a uniform standard. CMS requires QCDRs to submit their data in one format and the CMS standards should be a sufficient starting point. It must be recognized that standards evolve over time and may be inappropriate to mandate a specific standard through legislation, especially as technology evolves.

- Clinical Data Definitions. There is a need to define clinical data definitions so any time a data element is captured/exchanged it means the same thing across registries and EHRs. There are some registries, large health systems, and third-party vendors who have begun this work. However, if every society, health system and vendor creates these standards, we still will not have a set of national standards. By requiring EHR vendors, registries and all other electronic data systems for performance measurement/evaluation and clinical decision support to use standard definitions it would facilitate "semantic" interoperability.

- Standard Formats. There is the need for the most common data elements to be standardized in a universal format. For example, date of birth can be entered as 012915 or January 1, 2015, into the EHR and/or registry. This level of variability makes it difficult to query and exchange data across systems. Here "syntactic" interoperability, like semantic interoperability, requires the establishment of standard data formats so that two exchanging systems know how the data should be formatted and incorporated.

- Functional Standards. EHR data is in an unstructured free text format. To enhance quality, a third party and/or an individual needs to scrub and clean this information to make it meaningful. For example, when a patient complains of shortness of breath, this is simply typed into the EHR, but for performance improvement you need to know exactly what the patient means by shortness of breath. Is it shortness of breath because the patient just walked a mile or due to a particular condition? The functional status types of definitions have not been widely defined because it is neither needed nor relevant for payment. To begin this work, stakeholders must start with the most universal data elements and most commonly used standards.

The AMA and national medical specialty societies are ready to assist with this task. We welcome the opportunity to work with the Committee on a grant program at the Department of Health and Human Services to launch and maintain this work within the private sector in the interest of the public good.

Section 4381. Exempting from manufacturer transparency reporting certain transfers used for educational purposes

The AMA has been a staunch advocate of transparency in the interactions between physicians and industry and inclusion of the Physician Payment Sunshine Act in the Affordable Care Act. We believe that inclusion of this provision in the final Cures legislation is needed to remedy onerous and burdensome reporting obligations imposed by CMS that have already chilled the dissemination of medical textbooks,

peer-reviewed medical reprints and journals, and to avert a similar negative impact on access to independent certified and/or accredited continuing medical education (CME). This provision would ensure that efforts to promote transparency do not undermine efforts to provide the most up-to-date peer-reviewed medical knowledge, which through timely dissemination improves the quality of care patients. **The AMA strongly supports this provision.**

Sections 4281. Medicare Part D Lock-In

The AMA has long advocated for public policy solutions that will combat prescription drug diversion, abuse, overdose and death. Supporting physician clinical decision-making at the point of care through modernized, up-to-date patient specific information on dispensed prescription medications has been a major public policy initiative that we continue to support because it is sensible, proven, and it works. The AMA is extremely concerned that a number of legislative proposals would limit clinical decision-making or prevent physicians from providing patients with necessary medical treatment and referral.

There have been a number of proposals for a Medicare lock-in program that would, for example, authorize Part D prescription drug plans (PDPs) to determine that certain patients are misusing controlled substances, and then impose coverage limits so patients could only obtain controlled substance prescriptions from one physician and have them filled at one pharmacy. In response to various iterations of the foregoing proposal, the AMA has noted that PDPs only have information about their subscribers' claims for Medicare-covered drugs; they do not know their health status, treatment plans, or diagnoses. Many problems would result from adoption of the policy. For example, hospitalized patients could be prevented from filling prescriptions provided at discharge because they were not from the designated prescriber. Patients may not be able to easily access a designated pharmacy or prescriber. Moreover, patients may be seeing more than one physician who legitimately prescribes needed controlled substances. The proposal to lock-in certain Medicare beneficiaries is not a proven strategy, could be expanded without adequate justification, is premised on the faulty assumption that insurance company decisions to lock-in patients to certain providers and/or pharmacies could actually be appealed in a timely way, and fails to account for a significant and carefully tailored set of policies that are already working in the Medicare Part D prescription drug program.

The AMA has been actively engaged with CMS, along with other stakeholder organizations representing providers and patients on Medicare Part D issues, and submits comments every year on draft guidance issued for Part D plans. For cost year 2013, CMS authorized Part D plans to implement utilization measures to address outliers in opioid analgesic prescribing/dispensing. The Medicare Part D Overutilization Monitoring System (OMS) was implemented on July 31, 2013, to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of prescribed medications as required by regulation. This represented a second round of guidance issued to plans that began in 2011 for cost year 2012. The AMA provided comments to modify and target utilization review for outliers of opioid analgesics and emphasized the importance of communicating with prescribers where: (1) multiple prescribers were involved and may have been unaware of existing prescriptions issued by others; or (2) prescriber DEA number had been illegally used. Part D plans have been authorized since cost year 2013 to employ utilization review and directed to communicate with prescribers and, if necessary, beneficiaries prior to implementing point-of-sale edits or point of sale denials. While this places the burden on payers—Part D plan—to communicate with prescribers and pharmacies, it is an appropriate alternative to imposing substantial burdens on patients

who may be inappropriately locked-in and their health care providers who have to contend with a broken Part D appeals process that all major stakeholders agree is not functional.

Section 4281, like earlier Part D lock-in proposals, suffers from a number of infirmities that will harm patients and their access to medically necessary medication. First, this provision is overly broad and could eliminate pharmacy choice for a large number of beneficiaries. Unlike other lock-in proposals, Section 4281 would authorize PDPs to initiate lock-in without evidence that a patient is misusing, abusing, or diverting their medication, only that they have obtained coverage for medication that the plan believes has a potential for fraud or abuse. (Section 4281 does not limit PDPs to medications that are demonstrated to be diverted, abused, or misused by the Centers for Medicare & Medicaid Services, for example.) PDPs are not required to first notify prescribing physicians that the appropriateness of the prescription(s) are in question—instead PDPs are authorized to notify beneficiaries even though PDPs do not have access to the patient's medical record. Second, this provision would permit PDPs to lock the patient into the pharmacy of the PDP's choice. The foregoing is a glaring and obvious conflict of interest where plans are able to select pharmacies based on cost as opposed to patient accessibility. Furthermore, PDPs are not required to do anything more than what they currently do to monitor use of medications by their beneficiaries. PDPs are not required to provide any assistance to beneficiaries. These provisions are not designed to promote improved patient health outcomes nor to stop misuse, abuse, or diversion of covered Part D medication. In contrast, the OMS program includes an effective mechanism to facilitate communication between all relevant prescriber(s) and the PDP and ensures that clinical considerations are the basis of subsequent prescriptions and necessary therapeutic interventions. **The AMA strongly urges the Committee to remove this provision from the final legislation.**

Sections 2061-2063. Sensible Oversight for Technology which Advances Regulatory Efficiency

The transformation of medicine is already well underway and driven by the rapid uptake and use of digital health products and the software that supports these devices. The AMA supports efforts to increase regulatory flexibilities that are essential for innovation to occur. The AMA has generally welcomed the prodigious efforts of the FDA to update oversight and guidance in the digital health space to better reflect the appropriate balance between risk and benefits as well as the need to adopt a risk-based approach given the finite Agency resources and the looming wave of products and devices under development. We also appreciate that regulatory certainty is essential to ensure that developers understand the rules of the road and are able to forecast and plan an appropriate development pathway. It is for this reason the AMA is interested in sections 2061-2063 which would create a completely new regulatory framework. Directing the FDA to develop new regulations could delay finalization of the oversight structure for at least two to three years, potentially. **In addition, the AMA does have questions related to the risks that physicians would assume under the proposed framework under Sections 2061-2063.** These provisions also raise issues that are directly related to the Precision Medicine Initiative, and we would welcome the opportunity to discuss with the Committee.

Section 2088. Access to CMS Claims Data for Purposes of Fraud Analytics

AMA policy supports fraud prevention that is targeted and conducted by appropriate authorities. This section would allow authorized third parties to have real time access to claims data for fraud prevention. **The AMA would not support this provision since the U.S. Department of Health and Human Services Office of the Inspector General, the CMS contractors, the U.S. Department of Justice, and state Medicaid Fraud Units have access to this information and have appropriate safeguards and**

capabilities in place. Expanding access to entities without existing safeguards and less accountability to the public will only result in poorly targeted fraud efforts and other unintended consequences, such as identify theft.

Section 4241. Treatment of Global Surgery Services Rule

In the 2015 Final Medicare Physician Fee Schedule Rule, CMS finalized a policy to transition 10– and 90–day global period codes to 0-day global period codes in 2017, and 2018, respectively. Because the current CMS policy will have a wide-ranging impact on patients, physicians, hospitals, third-party payers, and Medicare, we appreciate that the Committee has included a provision that would prevent implementation of this policy. Global codes include necessary services normally furnished by a surgeon before, during, and after a surgical procedure. Global codes are classified as 0-day (typically endoscopies or some minor procedures), 10-day (typically other minor procedures with a 10-day post-operative period), or 90-day (typically major procedures with a 90-day post-operative period). Approximately 4,200 of the over 9,900 Current Procedural Terminology (CPT) codes are 10- or 90-day global codes. Despite the fact that the policy will affect 10-day global codes in 2017 and 90-day global codes in 2018, CMS has not yet developed a methodology for making this transition. The Agency has stated that it does not know how best to proceed. Nevertheless, CMS must begin to transition all these codes no later than February 2016. Implementation of this policy has consequences related to the objectives of the 21st Century Cures Initiative because, among other problems, it obstructs clinical registry data collection and quality improvement initiatives and will likely negatively impact patient care as it creates disincentives to follow-up care through imposition of additional co-pays. **The AMA strongly supports the inclusion of section 4241 in the bill that will be introduced.**

The AMA appreciates the opportunity to provide comments on the 21st Century Cures initiative and looks forward to working with you and the Committee to ensure the proposed policies support and promote physicians' ability to practice medicine in the innovative health care environment of the 21st Century through new technologies and cures.

Sincerely,

[redacted]

James L. Madara, MD

Roger Jordan, O.D., F.A.A.O.
Chairman, Federal Relations Committee

February 10, 2015

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Building
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
2368 Rayburn House Building
Washington, DC 20515

Re: 21st Century Cures Discussion Document

Submitted electronically via cures@mail.house.gov

Dear Representatives Upton and DeGette,

The American Optometric Association (AOA) appreciates your ongoing efforts to work together and with doctors of optometry and other physicians to advance smart health care solutions that positively impact the lives of millions of Americans. We thank you for this opportunity to provide input regarding the 21st Century Cures discussion draft. Overall, we believe that Congress has an important role to play in defining what steps can be taken to accelerate the pace of cures in America – from the discovery of clues in basic science, to streamlining the drug and device development process, to unleashing the power of digital medicine and social media at the treatment delivery phase. Generally, the AOA supports the 21st Century Cures effort and - along with our broad support – we offer thoughts below regarding specific sections of the discussion draft as well as strategies which we believe should be incorporated into the draft to better ensure that Medicare patients with diabetes receive cost-saving and quality of life-improving primary and preventive eye health and vision care. We thank you for your interest in this important topic and look forward to continuing to work with you and other leaders in Congress as you continue to consider strategies aimed at better meeting the health care needs of families in communities across America.

The AOA represents approximately 33,000 doctors of optometry and optometry students. Doctors of optometry are eye and vision care professionals who diagnose, treat and manage diseases, injuries and disorders of the eye, surrounding tissues and visual system and play a major role in a patient's overall health and well-being by detecting and helping to prevent complications of systemic diseases such as hypertension, cardiovascular disease, neurologic disease, and diabetes - the leading cause of acquired blindness. Doctors of optometry serve patients in nearly 6,500 communities across the country, and in 3,500 of those communities we are the only eye doctors available. Providing more than two-thirds of all primary eye and vision health care in the United States, doctors of optometry deliver up to 80 percent of all primary vision and eye health care provided through Medicaid. Recognized as Medicare physicians for more than 25 years, doctors of optometry provide medical eye care to nearly nearly six million Medicare beneficiaries annually.

Reducing Medicare Costs and Improving Seniors' Lives by Ensuring Prevention and Early Diagnosis and Treatment for Diabetic Eye Diseases

Today, nearly 30 million Americans are thought to be suffering from diabetes, with nearly 8 million unaware that they even have the disease. Among the Medicare population, the prevalence of diabetes is growing at an alarming rate, with nearly 12 million seniors affected by the disease. According to the Centers for Medicare & Medicaid Services, at least 32 percent of overall Medicare spending is attributed to the diabetes population. In Americans under the age of 74, diabetes is the leading cause of vision loss. Often there are no visual symptoms in the early stages of many diabetic eye diseases, including diabetic retinopathy – the leading cause of blindness among diabetics. Additionally, seniors and others with diabetes are at higher risk for a range of diabetes-related eye diseases, including cataract and glaucoma. That is why it is important that those diagnosed with diabetes have an initial comprehensive dilated eye examination performed by an eye doctor after the onset of diabetes and regular comprehensive dilated eye exams performed by an eye doctor thereafter. Early detection and treatment can limit the potential for significant vision loss and even blindness while saving Medicare and other health care efforts from costs associated with delayed diagnosis and treatment.

As part of the Cures package, the AOA urges lawmakers to include a new provision aimed at the prevention of diabetic eye disease. This provision would amplify what is currently being done on a limited basis by physicians in the Physician Quality Reporting System (PQRS) and by Accountable Care Organizations (ACOs) in the Shared Savings Program. Such an effort would incentivize primary care providers to refer patients with diabetes to local eye doctors for comprehensive dilated eye exams. Eye exams for

patients with diabetes can lead to overall lower spending on health care, which is evidenced here. Recognizing the importance of preventive eye care in helping to ensure early diagnosis and treatment of patients with diabetes, there are quality measures that currently exist to evaluate the eye care provided to those patients. Those measures seek to evaluate not only the care provided to the patient, but also whether there is adequate care coordination and communication among the diabetes care team members. Current PQRS measure 19 (NQF 0089) "Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care" captures whether clinicians who provide the primary management of patients with diabetic retinopathy appropriately communicate to the physician who manages the ongoing care of the patient. Current PQRS measure 117 (NQF 0055) "Diabetes: Eye Exam" seeks to capture whether patients diagnosed with diabetes receive necessary retinal or dilated eye exams. Beginning this year, ACOs participating in the Medicare Shared Savings Program are being held accountable for their physicians to report PQRS measure 117 to make sure Medicare patients with diabetes have annual comprehensive dilated eye examinations. While these quality measures are a step in the right direction toward ensuring that patients with diabetes receive timely diagnosis of diabetic eye diseases and necessary follow-up eye care, more needs to be done to ensure that the millions of Americans who currently are suffering from diabetes have their eyes examined annually.

According to the most recent data from CMS, only 36.3 percent of eligible professionals are participating in PQRS and a smaller number of providers are ACO participants. This means that the Medicare program is now missing important diagnosis and treatment opportunities for a large percentage of beneficiaries already at a higher risk for a range of diabetic eye diseases. This creates higher costs for the Medicare program and lower quality of life for America's seniors. As such, the AOA believes that lawmakers should include within Cures a provision that would provide incentives for primary care providers to refer Medicare patients diagnosed with diabetes for comprehensive dilated eye exams performed by an eye doctor. Such an effort could require a report from the eye doctor back to the primary care provider with the results of the findings within a set amount of time. AOA would be willing to assess the progress and recommend additional strategies for ensuring that all Medicare patients diagnosed with diabetes receive annual comprehensive dilated eye exams to help limit costs and the potential for significant vision loss and even blindness among Medicare beneficiaries.

Needed Reform of Local and National Coverage Decisions

The AOA believes that reform of local and national coverage decisions is needed and we applaud lawmakers for including a provision toward this end within the Cures draft. The AOA continues to witness the damage that improper coverage decisions can have on providers and their patients. A few years ago, a Medicare Administrative Contractor

improperly used a local coverage determination (LCD) to limit Medicare beneficiaries' statutory freedom of choice and access to care. The MAC medical director attempted to overrule state law by inserting his own flawed opinion about the scope of practice of a doctor of optometry. After Congress questioned this abuse of authority, CMS leadership ultimately stepped in to confirm that the state is the authority on the scope of practice of its licensees. Although coverage determinations are properly viewed from the perspective of the patient, the MAC attempted to use an LCD to inappropriately deny coverage for a range of covered physician services which doctors of optometry are legally authorized to perform under state law. As a result, seniors were improperly denied access to medically necessary care they needed when they chose to legally obtain those services from doctors of optometry rather than from other, often less-capable physicians.

The AOA and leading lawmakers objected to these actions as the Social Security Act requires Medicare to cover physician services, including services provided by doctors of optometry within state scopes of practice (Section 1861 of the Social Security Act). Medicare beneficiaries also have the "basic freedom of choice" to obtain health services from any qualified health care provider (Section 1802(a) of the Social Security Act). Also, AOA and lawmakers objected because Medicare beneficiaries have the right to have such services judged by objective clinical standards to determine if they are "reasonable and necessary" for coverage purposes (Section 1862(a)(1)(A) of the Social Security Act). The role of the MAC is to responsibly make those types of clinical coverage assessments after consultation with the respective heath care provider groups (Section 1874A of the Social Security Act). However, the AOA and lawmakers objected because under statue it is not the role of the MAC to determine what is or not within the state authorized scope of professional practice under the guise of establishing what services are clinically reasonable and necessary. That legal function is squarely and exclusively the responsibility of the states issuing the license to practice optometry, usually delegated to the purview of the state licensing boards.

In short, the AOA remains concerned that MACs may again attempt to supersede state authority to determine optometric scope of practice. These actions only serve to restrict patient access to a range of services which doctors of optometry are legally authorized to perform, and to misuse Medicare policy to protect other physicians from competition by optometrists. While CMS has admonished a contractor for creating such a list of codes, we believe that congressional action is needed to ensure that MACs respect state authority to determine scope of practice. We will submit additional language to add to the amended Section 1862(l)(5)(D) in the legislation.

For example, we recommend adding subsection (vii) to the end of the proposed amended Section 1862(l)(5)(D):

‘‘(vii) STATE SCOPE OF PRACTICE.—A Medicare administrative contractor may not use an LCD to limit Medicare beneficiary freedom of choice to choose a physician duly licensed in the state to provide a covered physician service. A Medicare administrative contractor should defer to the appropriate state authority about the scope of practice for a physician in the state.

Ensuring Appropriate Telehealth Services and Protecting Patients from Inappropriate Use

Telehealth services might be beneficial to patients and providers in some circumstances. When used appropriately, the technology can offer new access points for those living in remote or other underserved areas, where providers are often scarce or non-existent. It can help health care providers better communicate with their patients and with their colleagues as well as the broader interdisciplinary health care team. And, it can also help doctors monitor patients with a diagnosed disease, meaning closer and more convenient observation of disease and the impact of treatment. In fact, the AOA supports the use of telehealth to provide greater interaction between patients with diagnosed disease and their eye care provider. For instance, optometry has long-participated in telehealth efforts to monitor diabetic patients for progression of diabetic retinopathy. However, while telehealth might offer some benefits, it also has serious drawbacks when it is not used appropriately, including the potential for disrupting the doctor-patient relationship and putting patients at an increased risk for delayed or even completely-missed diagnosis and care opportunities. This is especially true when telehealth is used as a replacement for an in-person comprehensive eye health and vision exam provided by an eye doctor, which is the only preventive and primary eye and vision care intervention that can diagnose and ensure treatment for the complete range of eye health and vision care issues that may impact a patient.

The AOA supports many of the ideas behind the Cures provisions stemming from the *Advancing Telehealth Opportunities in Medicare Act*. We support use of telehealth services within the Medicare program, especially when augmenting services that can be easily interchanged with little or no patient impact. We believe that telehealth has great potential to serve the needs of the public and that it should be encouraged, but only when used appropriately. However, we strongly believe that telehealth should never be used as a substitute for an in-person comprehensive eye health and vision exam provided by an eye doctor nor to bypass doctors who are available to the patient to provide face-to-face care. It may be used to help monitor diseases including eye diseases, though only for those with diagnosed disease and in-between regular comprehensive eye health and vision exams. The only way to truly ensure a patient’s eye and vision health is through regular comprehensive eye health and vision exams, which cannot be substituted with a telehealth service.

As such, we would urge changes to the Cures section's "list of services" for telehealth recognition and payment under Medicare and the inclusion of "telehealth services that are a substitute for an in- person visit." Overall, we feel that these sections need to be made clearer. We believe that Congress must make it clear that the telehealth service can only substitute for an in-person visit when those services are interchangeable and will not negatively impact the patient, or when there is no access to a provider who can provide the service face-to-face. For example, when a disease specific telehealth eye screening is done in place of comprehensive eye health and vision exam provided in-person by an eye doctor, the patient may lose out of the opportunity for diagnosis and early treatment of many other eye and vision problems that they may not know that they have, including a wide range of eye disease that can be successfully diagnosed and treated when identified early. We also share similar concerns with "allowing a patient to be moved to a lower level of care." We feel this must be more clearly defined to ensure that the lower level of care is what is best for patients and not simply a lower level of service or simply a less costly but not appropriate service.

AOA also believes that the sense of Congress urging "state medical board compacts" should also be made clearer to ensure that doctors of optometry are not impacted by medical boards creating compacts to develop common licensure requirements. Doctors of optometry are generally regulated by Boards of Optometry, which are not defined as "state medical boards." We believe that the language must clarify that doctors of optometry will not be subject to the decisions of the states on regarding these compacts because optometrists are overseen by their own boards. Another avenue to improve this language would be to change "state medical boards" with "state health care provider boards." This would ensure that medical doctors and other providers were able to help shape and participate in the appropriate use of telehealth services.

With respect to the draft provision to prevent CMS from eliminating global payments for surgical procedures, the AOA urges caution. While tepidly supporting the CMS plan, the AOA warned the Medicare agency that eliminating global periods would not necessarily have the result intended. The AOA believes global payment policies act to restrain services and spending, and removing the bundled payment would allow for more accurate (but not less expensive) claims overall. However, given the strong opposition by some members of the physician community, the AOA believes some physicians appear to fully expect to be paid less when CMS begins applying the new policy.

As you continue to consider changes and additions to the 21st Century Cures package, along with other changes, the AOA urges you to work toward a legislative product that

includes a provision to better ensure that Medicare patients with diabetes receive cost-saving and quality of life-improving primary and preventive eye and vision care and language which guarantees that inappropriate uses of telehealth do not disrupt the doctor-patient relationship and place patients at greater and unnecessary risk for delayed or even completely-missed diagnosis and care opportunities. On behalf of our membership and the millions of patients that doctors of optometry serve each year, we thank you for considering these comments and using our feedback to improve the 21st Century Cures discussion document. Please contact Matt Willette at mwillette@aoa.org or (703) 837-1001 if you have questions or need additional information about these comments.

Sincerely,

Roger Jordan, O.D., F.A.A.O
Chairman, Federal Relations Committee
American Optometric Association